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APPLICATION DATA SHEET

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TRANSMITTAL

Electronic Version v1.1

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Title of Invention	INJECTION DEVICE FOR ADMINISTERING A VACCINE							
<p>Application Number :</p> <p>Date :</p> <p>First Named Applicant: Eric James Wall</p> <p>Confirmation Number:</p> <p>Attorney Docket Number: CHM-021P</p>								
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<table border="1"><thead><tr><th data-bbox="131 993 773 1031">Submitted By:</th><th data-bbox="773 993 1112 1031">Elec. Sign.</th><th data-bbox="1112 993 1414 1031">Sign. Capacity</th></tr></thead><tbody><tr><td data-bbox="131 1031 773 1108">Daniel Frederick Nesbitt Registered Number: 33746</td><td data-bbox="773 1031 1112 1108">/danielfredericknesbitt/</td><td data-bbox="1112 1031 1414 1108">Attorney</td></tr></tbody></table>			Submitted By:	Elec. Sign.	Sign. Capacity	Daniel Frederick Nesbitt Registered Number: 33746	/danielfredericknesbitt/	Attorney
Submitted By:	Elec. Sign.	Sign. Capacity						
Daniel Frederick Nesbitt Registered Number: 33746	/danielfredericknesbitt/	Attorney						

Documents being submitted:	Files
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us-fee-sheet	CHM021P-usfees.xml us-fee-sheet.xsl us-fee-sheet.dtd
application-body	CHM021P-trans.xml us-application-body.xsl application-body.dtd wipo.ent mathml2.dtd mathml2-qname-1.mod isoamsa.ent isoamsb.ent isoamsc.ent isoamsn.ent isoamso.ent isoamsr.ent isogr3.ent isomfrk.ent isomopf.ent isomscr.ent isotech.ent isobox.ent isocyr1.ent isocyr2.ent isodia.ent isolat1.ent isolat2.ent isonum.ent isopub.ent mmlextra.ent mmlalias.ent soextblx.dtd CHM021P01.tif CHM021P02.tif CHM021P03.tif CHM021P04.tif CHM021P05.tif CHM021P06.tif CHM021P07.tif CHM021P08.tif CHM021P09.tif CHM021P10.tif CHM021P11.tif CHM021P12.tif CHM021P13.tif CHM021P14.tif CHM021P15.tif

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Comments

Description

[INJECTION DEVICE FOR ADMINISTERING A VACCINE]

BACKGROUND OF INVENTION

[0001] The present invention relates to injecting vaccines and other medication and, more particularly, to an injection device that can be used in a method for administering vaccine injections painlessly for a patient.

[0002] Conventional medical injection devices for injecting medication into the muscle or tissue of a patient typically comprise some form of a manual hypodermic syringe. Generally speaking, a hypodermic syringe consists of a cylindrical barrel having a chamber that provides a reservoir for a liquid medication, a distal end adapted to be connected to a hollow hypodermic needle and for placing one end of the needle into flow communication with the medication contained within the chamber, and a proximal end adapted for receiving a stopper and plunger assembly. The stopper and plunger assembly includes a stopper ef-

fective for moving along the barrel chamber and an elongated plunger effective for causing movement of the stopper. The needle of the hypodermic syringe is manually inserted into the patient through the skin. The stopper is moved along the barrel chamber by applying axial force to the plunger, thereby forcing the liquid medication out of the barrel chamber, through the hypodermic needle and into the muscle or tissue of the patient.

[0003] Receiving an injection by such a conventional device can be a very traumatic experience, particularly for a child. The child's fears, and that of the child's parent, can become a significant medical problem if it leads to the child not receiving a required vaccination. These fears are predominately caused by pain which is associated with injections given by conventional injection devices and methods.

[0004] Studies have shown that the pain associated with an injection is related to the size of the needle and the flow rate at which the medication is injected. It has been found that the amount of pain or discomfort experienced by a patient increases as the outside diameter of the needle increases. It has also been found that high flow rates of medication injection (e.g., about 0.5–2 ml per second) into the patient

can tear internal tissue and cause pain. The tearing of tissue is caused by the build-up of excessive pressure within the tissue when the surrounding tissue is unable to quickly absorb the injected medication.

[0005] While the injection of a medication at a relatively slow flow rate is more comfortable for the patient, the increased amount of time the syringe remains in the hand of the medical personnel can make the technique tiring for such personnel as well as the patient. In addition, small vibrations or disturbances of the needle caused by movement of the medical personnel or the patient can result in pain to the patient. It is known that the fluctuation of flow rate of the injection of medication being delivered by a hand-held syringe can vary greatly. It is extremely difficult, if not impossible, to deliver a steady, very slow flow of medication from a hand-operated syringe (the human thumb depressing the syringe plunger) over an extended amount of time.

[0006] It has also been found that the sight of the hypodermic needle by itself is often enough to cause many patients to become anxious and tense. This reaction in turn may cause the patient's muscles to become tight and hard, making needle penetration even more difficult and

painful.

[0007] A number of methods and devices have been developed for reducing or eliminating the pain and discomfort associated with medical injections. One such method includes the application of a topical anesthetic to the injection site on the patient's skin prior to the injection, which itself can be painful. While this method has reduced some of the discomfort associated with injections, the topical anesthetic does not substantially penetrate the skin into the deeper skin and muscle tissue. Substantial pain and discomfort with intramuscular injections can remain.

[0008] Another technique for reducing the pain and discomfort associated with medical injections includes the step of injecting an anesthetic at the site of the injection using a fine gauge needle, then inserting the larger medication hypodermic needle through the anesthetized skin to inject the medication at a constant and slow flow rate intramuscularly at the desired depth. Unfortunately, injecting an anesthetic into a patient is not always desirable and the technique is relatively expensive and impractical for many routine injection procedures.

[0009] In addition to reducing pain or discomfort to the patient, safety has also become a principal concern to medical

personnel. Special precautions must be taken to avoid accidental needle sticks that could place a user at serious risk because of the danger from fluid borne pathogens. Despite the taking of special precautions, there still remains the possibility of an accidental needle contact and attendant injury. Accordingly, medical injection devices should operate to minimize the possibility of injury caused by accidental needle sticks.

[0010] In recent years, increased emphasis has been placed on establishing treatment protocols aimed at providing a patient as well as medical personnel with greater freedom of movement. To this end, there is a great deal of interest in the development of light weight and easy-to-use portable injection devices.

[0011] Accordingly, a need exists for substantially painless method and an apparatus for performing the method of injecting medication into a patient that does not require the use of an anesthetic, that does not require the medical personnel to spend a substantial amount of time performing a particular procedure, that is relatively simple, portable and inexpensive to perform and operate, that permits the patient a relatively high degree of movement during the injection, and that provides a relatively high

degree of safety for both the medical personnel and for the patient.

SUMMARY OF INVENTION

[0012] The present invention relates to an injection device that is manually-powered and configured for self-administering a vaccine painlessly. The device can be used in a method for providing a substantially painless injection of medication to a patient that does not require the use of an anesthetic, that does not require the medical personnel to spend a substantial amount of time performing the injection procedure, that is relatively simple and inexpensive to perform and operate, and that provides a relatively high degree of safety for both the medical personnel and for the patient.

[0013] The present invention also relates to a manually-powered injection device for painless inter-muscular injection of a vaccine, comprising a) a housing having a base for semi-permanent attachment to the skin of a patient, b) an injection needle disposed substantially perpendicular to the base and within the housing, the needle having an injection end, and configured for axial movement between a first position wherein the injection end is within the housing and a second position wherein the injection end ex-

tends outwardly from the base to a distance sufficient for intramuscular insertion thereof, the injection needle having an outside diameter greater than 0.20 mm and less than about 0.38 mm, c) a reservoir containing a vaccine, d) a means for liquid communication between the reservoir and the injection needle, e) a manually-powered means for inserting the injection needle to its second position, and f) a means for injecting the vaccine from the reservoir to the injection end of the needle.

BRIEF DESCRIPTION OF DRAWINGS

- [0014] Figure 1 shows a cross-sectioned elevation view of a housing of a manually-powered painless injection device of the present invention in an extracted position, taken through line 1-1 of the housing shown in Figure 4.
- [0015] Figure 2 shows the cross-sectioned elevation view of Figure 1 of the housing in an inserted position.
- [0016] Figure 3 shows a cross-sectioned elevation view of the housing shown in Figure 4, taken through line 3-3 of Figure 4.
- [0017] Figure 3A shows a detailed cross-sectional view of the housing of Figure 3.
- [0018] Figure 4 shows a top plan view of the housing of the manually-powered painless injection device.

- [0019] Figure 5 shows a cross-sectioned elevation view of the housing of Figure 4, taken through line 5-5.
- [0020] Figure 6 shows a cross-sectioned elevation view of the housing of Figure 4 taken through line 6-6.
- [0021] Figure 7 shows a cross-sectioned plan view of the housing of Figure 1, taken through line 7-7.
- [0022] Figure 8 shows a cross-sectioned plan view of the housing of Figure 1, taken through line 8-8.
- [0023] Figure 9 shows an exploded cross-sectioned elevation view of the elements of the housing of Figure 1.
- [0024] Figure 10 shows a cross-sectioned elevation view of a syringe cartridge of a manually-powered painless injection device of the present invention in an extended position, taken through line 10-10 of the syringe cartridge shown in Figure 12.
- [0025] Figure 11 shows a cross-sectioned elevation view of the syringe cartridge in an extended position, taken through line 11-11 of Figure 12.
- [0026] Figure 12 shows a plan view of the syringe cartridge of Figure 10.
- [0027] Figure 13 shows a detailed cross-sectional elevation view of the syringe cartridge of Figure 10.
- [0028] Figure 14 shows another detailed cross-sectional eleva-

tion view of the syringe cartridge of Figure 10.

[0029] Figure 15 shows a plan view of the syringe cartridge shown in Figure 14.

[0030] Figure 16 shows a cross-sectioned plan view of the syringe cartridge of Figure 11.

[0031] Figure 17 shows a bottom plan view of the syringe cartridge of Figure 11.

[0032] Figure 18 shows an exploded cross-sectioned elevation view of the elements of the syringe cartridge of Figure 10.

[0033] Figure 19 shows a cross-sectioned elevation view of the syringe cartridge of Figure 10 containing vaccine in a pressurized position.

[0034] Figure 20 shows a cross-sectioned elevation view of the housing and a separable base assembly prior to its attachment to the housing, and of a syringe cartridge prior to its installation into the housing.

[0035] Figure 21 shows the housing and syringe cartridge of Figure 20, with the housing being affixed to a patient's skin.

[0036] Figure 22 shows the syringe cartridge being installed into the housing of Figure 21.

[0037] Figure 23 shows the syringe cartridge being force into an inserted position within the housing.

[0038] Figure 24 shows the syringe cartridge in the inserted po-

sition within the housing, injecting vaccine.

[0039] Figure 25 shows the syringe cartridge in the inserted position within the housing, at the completion of the vaccine injection.

[0040] Figure 26 shows the syringe cartridge in the inserted position within the housing of Figure 25, being manipulated to retract the needle.

[0041] Figure 27 shows the syringe cartridge and housing of Figure 26, with the needle retracted.

[0042] Figure 28 shows the housing and the syringe cartridge of Figure 27 being removed from the separable base that remains attached to the patient.

[0043] Figure 29 shows a top plan view of another embodiment of the invention, of a device having a housing that can accommodate two syringe cartridges.

[0044] Figure 30 shows an elevation view of the device of Figure 29.

[0045] Figure 31 shows a cross-sectioned elevation view of the dual-syringe device of Figure 29 taken through line 31-31.

[0046] Figure 32 shows a separable base assembly having an adhesive flap for use in attaching the device of the present invention to the skin of a patient.

- [0047] Figure 33 shows a cross-sectioned elevation view of the separable base assembly of Figure 32 through lines 33-33.
- [0048] Figure 34 shows a detailed cross-sectioned elevation view of the separable base assembly of Figure 33.
- [0049] Figure 35 shows another detailed cross-sectioned elevation view of the separable base assembly of Figure 33.
- [0050] Figure 36 shows a cross-sectional plan view of a base shown in Figure 22 through lines 36-36, which has been modified to provide blocking plate that is in an deployment position to allow needle deployment.
- [0051] Figure 37 shows a cross-sectional elevation view of the base of Figure 36.
- [0052] Figure 38 shows a cross-sectional plan view of the base of Figure 36, which is in a blocking position to prevent needle deployment.

DETAILED DESCRIPTION

- [0053] Definitions: As used herein, "patient" means a person, including a child or infant, or an animal, typically a mammal, on which the device is used to inject a vaccine, or a person who uses the device on himself or herself.
- [0054] As used herein, unless specified otherwise, the term "upward" means in a direction or oriented away from the pa-

tient's skin or the base of the device; the term "downward" means in a direction or oriented toward the patient's skin or the base of the device; the term "inward" means in a direction or oriented toward the centerline of the device; and the term "outward" means in a direction or oriented away from the centerline of the device.

[0055] As used herein, unless specified otherwise, the phrase "manually powered" means that the power provided for the device of the present invention to at least insert the injection needle into the patient's skin is provided manually by a medical technician (a nurse, doctor, or other person who can administer the injection) or the patient, by manipulating the injection device with the hands or fingers, or by manipulating an appropriate implement.

[0056] As used herein, unless specified otherwise, the term "self-administering" describes the ability of the device of the present invention to be held in a position attached to the body of a patient by a securement means to the skin of the patient, without requiring medical personnel, the patient or other human, to hold the device, during the time that a vaccine supply contained within the device is injected into the patient through an injection needle.

[0057] The manually-powered, self-administering injection de-

vice of the present invention typically comprises a housing, an injection needle, a reservoir for containing a supply of a vaccine or other medicament, and a plurality of elements associated with and at least semi-permanently attached to the housing. The other associated elements can also include the various means of providing power or energy for the functional operations of the device, such as the insertion and retraction of the injection needle, and the pumping or injecting of vaccine to the injection needle. Typically, these associated elements are contained within the confines of the housing, although these elements can also partially confront or penetrate through the outer surface of the housing.

[0058] In the course of administering most injections of vaccines and other medicaments, the injection can be advantageously administered intramuscularly, that is, into the muscle. The injection is by an injection needle that is configured for insertion through the outer layer of the subject's skin, and more typically into the muscle tissue of the patient. Typically, the depth of insertion is at least about 5 mm, and typically up to about 35 mm or more, more typically from about 10 mm to about 25 mm, and even more typically from about 15 mm to about 20 mm. For a young

child or infant, the depth of insertion is typically from about 10 mm to about 25 mm, more typically from about 12 mm to about 15 mm. Alternatively, some injections can be administered intradermally, or into other internal organs or the general body cavity of the subject.

[0059] The manually-powered devices of the invention are intended to be attached semi-permanently to the skin of the patient before, during or after the injection. The devices are typically configured to be attached to the upper arm or to the thigh area, providing access to the larger skeletal muscles (the deltoids and the quadriceps) for intramuscular injection. The attachment is preferably semi-permanent, whereby the device can be removed reasonably easily from the skin, and the device does not move or migrate along the surface of the skin after attachment. In many situations, an adequate adhesive attachment is sufficient. Alternative attachment means can include strapping, such as with a buckle strap or with a "hook and loop" attachment means commonly referred to as "Velcro", or cuffing, as with a sphygmomanometer cuff. In an other alternative embodiment, a portion of the device, such as a bandage associated with the device or a portion of the base of the housing, can be configured to remain affixed

to the patient's skin after the housing of the device has been removed.

[0060] A typical adhesive for securing the device directly to the skin is a pressure sensitive adhesive (PSA). The direct-attaching PSA and the base where the PSA is affixed are typically configured whereby the PSA has an adhesive affixment to the device greater than the adhesive affixment to the skin. The PSA is typically configured for permanent affixment to the device, such that no PSA will remain adhered to the skin of the patient when the device, or at least the housing portion of the device, is removed from the skin. The PSA is also selected for a secure though releasable affixment to the skin. These criteria ensure that the device, or at least the bandage or base portion of the device, can be securely affixed to the skin for the vaccination procedure, and can be safely and efficiently removed from the skin thereafter.

[0061] Typically, the manually-powered device having a skin-attaching PSA will also include a release member, such as a release paper or film, which overlies the adhesive on its skin-contacting side. The release member is peeled from the PSA prior to attachment to the skin. After removal of the release paper, the exposed adhesive layer can be

placed against the patient's skin to attach the device thereto.

[0062] A main objective for initiating the development of the present injection was effecting a painless injection of vaccines and other medicaments. While pain can be a relative experience, typically the painless device of the present invention will, after having been secured to the skin of the patient, effect the insertion of the injection needle and injection of the vaccine into the body without any sensation or feeling of pain, and more typically without any sensation or feeling whatsoever. In other words, the patient in most situations will have no sensation that the device has inserted a needle into the body, or that the vaccine or other medicament is or has been injected into the body, except perhaps visually observing the device or touching the device with a hand, or feeling the attachment of the device to the outside of the skin.

[0063] Typically the manually-powered device is configured to complete the vaccination or injection of medicament into the subject utilizing a source of power or energy that is external to the device itself. The source of power can be provided by either a medical technician (a nurse, doctor, or other person who can administer the injection) or the

patient, typically by manually (or bodily) manipulating the injection device with the hands or fingers, or using an appropriate implement, as hereinafter described. The self-administering feature of the device and method of the invention enables injection of vaccines and other medications without requiring medical personnel to hold the device against the skin of the patient during the time that the vaccine supply is in liquid communication with the needle, and is being pumped from the device into the patient. The use of the device that self-administers a vaccine injection allows medical personnel to perform other tasks while the injection is being administered. The device also allows the patient to have freedom of movement for the minutes of time that the injection is being administered. Typically, the source of power for arming the manually-powered device from its unarmed configuration comprises a manual power. This can be the use of the hands or fingers of a technician or an adult patient to manipulate the device or elements thereof with force. The manipulating force can also be applied using an implement, such as a key, push rod, or other inanimate object. The manually-applied kinetic force is stored by a power means within the device as potential energy, which can, upon subsequent

activation, power one or more of the functions of the device. Typically, the external force used for the needle insertion function can also be used to store potential energy within the device, such as in a compressed spring or other biased resilient member. The external force can also be stored as electrical power or pneumatic power.

[0064] Typically, the device is manufactured and shipped to a use center, such as a clinic or hospital, with the needle insertion function in a first unarmed configuration. The unarmed configuration provides that the injection needle, which in its first position has its injection tip wholly within the housing, can not be intentionally or accidentally extended to a second position wherein the injection tip extends through the base of the device and outside the device. In the unarmed configuration, there is no potential energy source, such as a compressed wire spring, available to the needle insertion means. The unarmed condition can also be termed a fail-safe position, since, in this configuration, even a malfunction of the device will not allow the needle to extend from the housing. By contrast, a function or means, such as the needle insertion means, that is armed has potential energy stored on board the device, such as in a compressed, extended or torsioned

spring, or other power means. If this armed device is activated, such as when a actuation button is depressed, the potential energy of the power means is released as kinetic energy which can drive the needle insertion means to its second, extended position. If the device is shipped, stored, or handled in its second, armed configuration, there is a significant risk of an inadvertent, or even an intentional, activation of the needle insertion means. Consequently, the shipment and handling of the manually-powered device of the present invention in an unarmed configuration can avoid both an intentional and accidental needle sticks prior to its use in administering a vaccine. This improves the safety and security of the device during, storage, and pre-injection handling. In this configuration, at least the needle extension function (also called the insertion function when the needle tip extends into the skin of the patient) is unarmed.

[0065] Other functions, such as the pumping or injection means (for passing the vaccine to the injection needle) and the needle retraction means (to withdraw the needle from its second position in the body back to its first position in the housing) can be configured for shipment and storage as either armed or unarmed. Preferably, the power means for

the pumping means has an unarmed configuration, since this can avoid an accidental activation of the pumping of vaccine from the reservoir, which could prematurely empty the reservoir and render the device useless. Likewise, any needle retraction means is preferably shipped and stored in an unarmed configuration, to avoid the possibility of an unintentional or accidental activation, which in some embodiments may make the opposing needle insertion function inoperable.

[0066] The power means can be used to provide energy to one or more of the elements of the device, such as insertion and retraction of the injection needle, or pumping of the medicament. Two or more power means can be used to provide energy for different elements, such as where the injection needle is moved from one position to another by a first power means, and a liquid medicament is pumped from a reservoir to the injection needle by a different, second power means.

[0067] The device can be at least partially self-controlled, wherein at least one of the elements of the device can function automatically in response to the operation of another element.

[0068] The typical device of the present invention has a housing.

The housing comprises a base for placement against the skin of a patient for attachment. The base can have a contoured surface that generally conforms to the shape of the body or skin, to maintain the base surface in optimum confronting relationship with the skin. For example, the base of the device can have a slightly concave surface, which arches inwardly toward the interior of the housing.

[0069] The housing is typically made of a thermoplastic material that is light and inexpensive to manufacture, such as by molding, yet durable and resilient to gross deformation. Typical plastic materials can include polyethylene or polypropylene. The housing can be designed with a shape that is both aesthetically pleasing and functional to house the injection needle, reservoir, and other elements of the device. The housing can be made as a single part or as a plurality of parts configured to associate together in both either static or moving relation to one another.

[0070] The housing also provides a visual enclosure for the injection needle that keeps the needle out of sight of the patient at all times during the injection procedure in the presence of the patient. This reduces or eliminates the patient's apprehension or fear caused by the sight of a hypodermic needle, thereby reducing the tendency of the

patient's muscles to tighten and harden, which can make needle penetration more difficult and painful.

[0071] The housing also provides a physical enclosure for the injection needle that helps to avoid accidental needle stick, particularly after an injection, which could place a user at serious risk from fluid-borne pathogens. The device can be configured for use only once (unless completely disassembled and retrofitted), thereby minimizing the likelihood of reuse of a contaminated hypodermic needle. The device can also advantageously be configured wherein some parts or assemblies, such as the housing and its associated elements, can be reused.

[0072] The housing can also be configured to receive and secure the needle and optionally the reservoir of vaccine as a modular insert into the housing body. The housing can include two or more parts, at least one of which is movable relative to another, which can be configured into an open position wherein either the needle or the reservoir, or both, can be inserted into the body of the housing, or a closed position wherein the needle and/or reservoir are not accessible or retrievable from within the housing. The movable part can be a door or a panel that is movable to provide an access port into the housing. The door or

panel can be hinged or removably affixed to the housing, or can be slidable away from the access port.

[0073] The injection needle of the device provides for liquid communication of the vaccine passing from the reservoir of the device into the body tissue of the patient, from where the vaccine can dissipate into the surrounding tissue and throughout the body. The injection needle should be shaped and configured to provide painless insertion and painless injection of the vaccine. Generally an injection needle having a smooth circular outer surface and an outer diameter D of about 0.36 mm (28 gauge needle) and less can be inserted painlessly through the skin of a patient. For small children, infants and patients having more sensitive skin, an outer diameter D of about 0.30 mm (30 gauge needle) and less (31 gauge to 33 gauge), will typically ensure painless needle insertion.

[0074] Typically the injection needle is configured to be substantially linear or straight, from its tip toward the opposed inlet opening. The needle can be configured to be linear to its inlet end, or can be configured having a bent or curved portion near the inlet opening.

[0075] The needle size should be sufficiently large to allow passage of the required volume of liquid medicament into the

body within a period of time that is suitable to avoid causing pain. For a typical medicament volume of about 0.5 ml to about 1.0 ml, a substantially painless to completely painless injection can be achieved over an injection period of from about 1 minute to about 10 minutes, more typically from about 3 minutes to about 5 minutes. The volumetric flow rate is at least about 0.05 microliter per second $\mu\text{L/s}$, and up to about 50 $\mu\text{L/s}$. Typically, the volumetric flow rate is about 0.5 $\mu\text{L/s}$ to about 20 $\mu\text{L/s}$, and more typically about 1 $\mu\text{L/s}$ to about 4 $\mu\text{L/s}$. The injection needle should be sufficiently durable and axially rigid to avoid bending or breaking when inserted into the skin and muscle. Typically, a needle having an outer diameter of from 0.20 mm (33 gauge), more typically of from 0.23 mm (32 gauge), to 0.36 mm (28 gauge), is sufficiently painless, durable, and liquid conductive.

[0076] Typically, the injection needle is pre-installed into the injection device during its manufacture, prior to its distribution to at the facility or site where the injection shall occur. Although the device can be configured for installation of the injection needle at the use facility, the small, fine size of the injection needle may be difficult to manipulate into its position within the device. Likewise, after a vacci-

nation, the injection needle and the housing or assembly thereof to which the needle is secured can be disposed of in accordance with health and safety regulations and guidelines.

[0077] The vaccine is typically contained within the cavity of a reservoir, and flows from the reservoir to the injection needle during injection. The reservoir is typically positioned within the housing although the structure of the reservoir can also form a portion of the outer surface of the housing. The reservoir can have a rigid structure having a fixed volume with a moveable member, such as a plunger that defines a variable volume cavity. The reservoir can also have a flexible structure where its volume can decrease as its content of vaccine is removed therefrom. Typical materials for use in making the reservoir include natural and synthetic rubber, polyolefin, and other elastomeric plastics. The selection of the structure and material of construction of the reservoir will depend in part on the specific means of pumping the medicament from the reservoir to the injection needle. Selection of the material of the reservoir should also be chemically stable with the vaccine. In another typical embodiment, the reservoir can be affixed to the injection needle as part of a

vaccine product, for assembly into the device. A reservoir will generally have a volume sufficient to contain about 0.1 ml to about 3 ml of medicament. In a typical embodiment, the reservoir would hold about 0.5 ml to about 1.0 ml of medicament.

[0078] The reservoir will comprise an outlet port, typically comprising a penetrable membrane that can provide an airtight and leak-proof seal over the outlet opening of the reservoir during manufacture, shipment and storage of the vaccine reservoir, and that can provide a self-sealing, leak-proof joint when pierced by the inlet end of the needle or a separate piercing conduit at the time of the vaccine injection. A typical reservoir membrane comprises natural or synthetic rubber or a thermoplastic material. Alternatively, a wall of the reservoir can be adapted to allow penetration thereof by the piercing conduit, such as the inlet end of a needle.

[0079] A typical embodiment of a reservoir comprises a reservoir body having a cavity that has been pre-filled with a vaccine and sealed. The pre-filled reservoir can be assembled into the device during its manufacture. In this case, the device with the specific vaccine is labeled to identify the particular vaccine that is contained therein.

[0080] More typically, pre-filled reservoir will be configured for installation or insertion into the housing of the injection device at the facility or site where the injection will occur. The technician would typically remove the vaccine reservoir from a refrigerated storage area and insert it into the housing of the device. A vaccine identity label associated with the vaccine reservoir can be provided that is conveniently transferred to the patient's records.

[0081] Alternatively, a device comprising an empty reservoir can be filled by medical personnel with the appropriate quantity and type of medicament, prior to injection. Typically, this embodiment of the reservoir comprises a vaccine flow valve that has a self-closing, self-sealing opening to the cavity of the reservoir. The vaccine flow valve is typically an elastomeric or rubber material. The opening is typically a cylindrical member having a slit opening formed axially there through. The vaccine flow valve can be inserted into a bore formed in the sidewall of the reservoir that is slightly smaller diameter than the flow valve. A hypodermic needle of a syringe can be inserted through the slit opening to inject a dose of liquid vaccine into the cavity of the reservoir. When withdrawn, the slit opening closes and seals itself. When the device is used by medical personnel

as supplied from a manufacturer with the reservoir securely inserted within the housing, the device can have a companion flow valve disposed in the surface of the housing, or otherwise accessible to the medical personnel. If the reservoir is configured so that a portion of the reservoir is integral with the housing, then a single flow valve can be used, with an inlet accessible to the medical technician and an outlet into the cavity of the reservoir. Alternatively, the device can be configured with a second vaccine flow valve positioned in the housing, disposed adjacent to and aligned with the first flow valve disposed in the reservoir.

[0082] An important requirement of the liquid communication means is to ensure that the liquid vaccine can flow from the reservoir to the injection needle regardless of the specific orientation of the device. Typically, the attachment of the device to the skin of the patient can position the reservoir and the injection needle into a variety of relative spatial orientations that can sometimes require the liquid vaccine to flow upward against gravity, or that can position the outlet of the reservoir in an upward position, opposite the pool of medicament disposed in the reservoir.

[0083] Consequently, a preferred configuration of the reservoir and liquid communication means provides that the outlet

of the reservoir is maintained in communication with the remaining liquid vaccine in the reservoir. A typical configuration comprises a collapsible reservoir comprising an outlet that maintains liquid communication with any residual liquid vaccine present in the reservoir. This reservoir has an upper flexible wall that can be conformed to the volume of the liquid remaining therein. The reservoir typically contains little or no air or gas when filled with the supply of liquid vaccine and during the vaccine displacement and injection operation. Thus, the reservoir collapses to become essentially empty, terminating vaccine delivery. In like manner, when a non-flexible material is used for a reservoir such as a tube with plunger, as in a conventional hypodermic syringe, the displacement of the plunger empties the reservoir terminating delivery.

[0084] The housing can also comprise an outer support structure that confines and protects the reservoir from outside elements that might puncture it, and which can define the initial shape of the reservoir.

[0085] The reservoir can also be constructed of an elastomeric material that can be expanded in volume when fill with the liquid medicament supply, and holds medicament under pressure. After puncture by a piercing conduit, such

as the inlet end of the injection needle or an intermediate member that is in liquid communication, such as via tube, with the injection needle, the expanded reservoir can contract to reduce the effective volume of the reservoir as liquid vaccine is pumped there from. One or more of the walls of the reservoir can be made of an elastomeric material, while other walls or surfaces are made of other elastic or inelastic rubber or plastic material.

[0086] The reservoir can also comprise an adaptable structure having a means of varying its effective volume, such as a piston-plunger construction or an accordion construction, as in a bellows. In the embodiments described herein, a self-contained reservoir can be replaced with a more conventional syringe and plunger for storing and injecting the medicament to the injection needle.

[0087] Non-limiting examples of a reservoir of the present invention are those described in US Patent 5,527,288 (element 10), US Patent 5,704,520 (element 12), and US Patent 5,858,001 (elements 16 and 17), all such publications incorporated herein by reference.

[0088] A first embodiment of the invention is shown in Figures 1-3, 3A, 4-28. The device includes a housing, shown in Figs. 1-3, 3A, and 4-9, and a cylindrical syringe cartridge

shown in Figs. 10–19. The use and operation of the device for self-administering a painless injection is shown in Figs. 20–28. A device having a housing for a plurality of cylindrical syringe cartridges is shown in Figures 29–31. Figures 32–25 shows a separable base and means for attaching the device to a patient's skin.

[0089] Figures 1–8 show the assembled housing 10 in various views and aspects. Figure 1 shows the housing 10 having an outer body 11, a needle carriage 70, and a base 12 for placement of the device against the skin of a patient. The carriage 70 is configured for movement along an axial centerline 100 in a direction perpendicular to the base 12. The cylindrical carriage has a cylindrical recess 71 having a tapered bottom 78, that opens to a connector portion 73 having internal female threads. A needle 40 lies along the centerline 100 and is disposed through the axial center of a needle hub 72 that is secured to the connector 73. The inlet 42 end of the needle 40 extends within the connector 73 sufficiently below the opening in the tapered bottom 78 to prevent the sticking of a finger that may probe the recess. A retraction spring 76 is positioned about the centerline 100, having one end disposed within an annular groove 74 in the underside of carriage 70, and

the other end disposed around an annular flange 94 projecting up from the base 12. The needle 40 extends downward from the lower end of the needle hub 72 toward the base 12. The needle is completely within the housing when the carriage 70 when in the first retracted position shown in Figure 1.

[0090] In a second inserted position, shown in Fig. 2, the carriage 70 has moved axially toward a position proximate to the base 12 of the device, and the needle 40 extends downwardly and out through the opening 13 in the base. The guide wall 14 comprises an inwardly-projecting, axially-oriented elongated rib 19 that registers along its length with an axially-oriented peripheral groove 77 in the outer wall 75 of the carriage 70, shown in Figure 3, to prevent the carriage 70 from rotating within the guide wall 14. A retainer heel 86 is biased inward from an opening in the cylindrical guide wall 14. As the carriage 70 passes down the guide wall 14, the heel 86 is temporarily biased outward, allowing the carriage to pass. The retraction spring 76 is compressed between the bottom of the carriage 70 and the base 12. When the carriage arrives at the fully inserted position, the lower end flange 79 of the carriage has cleared past the heel 86, which returns to its in-

wardly-biased position, where it can secure the carriage 70 and the needle 40 in the inserted position, and secures the retraction spring 76 in a compressed state. The heel 86 is part of a release arm 80, described herein after.

[0091] Figure 4 shows a plan view of the housing 10 in its first retracted position, with selected cross-sectional views taken as Figures 1, 3, 5, and 6 to illustrate certain elements of the housing. Figures 7 and 8 are sectional views of the housing in Figure 1. An exploded view of the elements of the housing 10 is shown in Fig. 9.

[0092] The syringe cartridge 18 shown in Figures 10 and 11 comprises a syringe assembly 20 and a telescoping pressurizing assembly 30. The syringe assembly 20 comprises a syringe body comprising a cylindrical wall 21 that has an open upper end 25 and a tapering base 22 that has, at the lower end, an externally-threaded syringe hub 64 having an aperture 23. A cylindrical plunger 24 can be inserted through the upper opening for engagement with the wall 21. The plunger 24 and the syringe body define a reservoir cavity 66. The plunger 24 is typically a flexible, resilient rubber material that can form an effective liquid seal about its periphery with the sidewall 21 of the syringe. The plunger 24 is secured around a rigid plunger

plug 26 to maintain its cylindrical shape. As can be seen in greater detail in called-out Fig. 13, the inner surface of the syringe wall 21 has, at its upper end, a slight inwardly-extending rim 38 that can engage the upper end 43 of the outer wall of the plunger 24, which can prevent the plunger 24 from incidentally withdrawing from and falling out of the upper opening of the syringe wall 21. Nevertheless, the plunger wall 39 is sufficiently flexible to be inserted into or extracted out of the syringe opening by force. The threaded bore in the plunger plug 26 is provided for attachment of a stem (not shown) having a mating thread so that the plug and the plunger 24 secured thereto can be manipulated into and out of the syringe opening, and along the length of the syringe.

[0093] The telescoping pressurizing assembly 30 comprises a cylindrical body 31 that is closed at an upper end 34 and has an opening 32 at the lower end. The lower edge of the wall 31 has a pair of opposed mechanical engaging means shown as inwardly-extending ribs 36 that can engage an outwardly-extending rim 28 disposed on the upper end 25 of the syringe wall 21, to secure the pressurizing assembly 30 to the upper end 25 of the syringe assembly 20 in a first extended position, as shown in Figure 10. A

pressurizing spring 33 is restrained within the body 31 between an annular groove 35 at the closed end 34, and an annular groove 27 in the plunger plug 26. When the pressurizing assembly 30 is in the extended position shown in Figure 10, the pressurizing spring 33 is typically some minimal compression. Figure 11 shows the same syringe cartridge, taken in a sectional view perpendicular to Figure 10, which shows the plunger 24 with the spring 33 essentially fully extended to the bottom of the syringe body 21. In this configuration, a medical technician could remove the upper pressurizing assembly 30, and, using a threaded stem (not shown), could withdraw the plunger to draw in vaccine through the aperture 23 (having first removed the membrane plug 67, and reinserting the membrane plug thereafter).

[0094] The wall 31 of the pressurizing assembly 30 is configured to telescope axially over the outside of the syringe wall 21 to a second pressurizing position (the position shown in Figure 19), where the ribs 36 can engage a second set of outwardly-extending rims 29 disposed near the lower end of the syringe wall 21, shown in Figure 10. This would cause the closed end 34 of the pressurizing body 31 to compress fully the pressurizing spring 33 against the

plunger plug 26, which would cause the plunger 24 to move to the bottom 22 of the syringe 21 when no liquid is contained in the syringe. The engagement of the ribs 36 with the lower rims 29 retains cylindrical body 31 in the fully pressurized configuration. When the syringe 21 contains a volume of vaccine, as shown in Figure 19, the engagement of ribs 36 with rims 29 restrains the expansion force of the pressurizing spring 33, which exerts a downward force upon the plunger 24, and pressurizes any liquid vaccine in the cavity 66. When the cavity is put into liquid communication with the needle 40, the liquid vaccine can flow out of the cavity under pressure. The pressurizing spring 33 is configured and designed to maintain a relatively constant vaccine flow rate through the needle throughout the injection process. Figure 12 shows a plan view of the top end 34 of the syringe cartridge 18, with selected cross sections taken as Figures 10 and 11 to illustrate certain elements and aspects. Figures 13–17 provide additional detailed views of the syringe cartridge 18 shown in Figures 10 and 11. Figure 18 shows an exploded view of the elements of the syringe cartridge 18.

[0095] In a method of using the device of the invention, a device 1 is provided as shown in Figure 20 having a housing 10,

a syringe cartridge 18, and a separable base assembly 93. The three members are shown separated to illustrate, that prior to use as an assembled product, the components can be separated and visually inspected.

[0096] The separable base assembly 93 can then be attached manually to the base 12 of the housing 10. Prior to attachment of the device to a person, a release paper 111 that covers the separable base 92 and adhesive flaps 112, is peeled away and disposed of.

[0097] As shown in Fig. 21, the housing 10 can first be attached to the upper arm or leg of the patient P. The base 12 of the device is placed against the patient's skin at the injection site, and is secured to the patient by the adhesive on the underside of the adhesive flap 112 that extend outward from the periphery of the separable base 92. A top plan view of the separable base assembly 93 is shown in Figure 32, with a sectional view and detailed sectional views shown in Figures 33–35. The adhesive flap 112 extends outwardly from the periphery of the separable base 92, and is covered entirely on its slower surface with the release paper 111. The adhesive flap 112 comprises a first film layer 114 that is affixed on its upper surface to cover the entire skin-facing surface of the separable base 92,

and extends outward from the peripheral circumference of the base 92. The flap 112 has a PSA on its lower surface for attachment to the skin. Flap 112 also comprises a second film layer 115 that is shaped as a ring with an inner circular edge 116 and an outer edge 117. The inner edge 116 extends inwardly and is affixed, typically with the PSA, to the upper surface of the separable base 92 in-board of its circumferential edge. The second film layer 115 extends outwardly from the separable base 92, to overlap the first film layer 114 to its periphery, and there beyond to its outer edge 117. Typically, the adhesive flap layers 114 and 115 can be a flexible plastic film.

[0098] Alternatively, the second film layer 114 can be eliminated, and the underside of the separable base 92 can comprise PSA for direct-contact adhesion to the skin. Optionally a gauze bandage 113 can be secured to the underside of the separable base 92 over the opening 13.

[0099] After attachment of the device to the skin, a seal 105 is removed that covers the opening to the carriage recess 71 to protect the needle 40 from contamination. As shown in Figures 21 and 22, the syringe cartridge 18 is then inserted into the recess 71 of the carriage 70. The threaded syringe hub 64 engages the threaded connector 73, so

that manual axial rotation of the syringe cartridge 18 mates the respective threads and secures down the syringe cartridge 18 to the carriage 70. As that occurs, a membrane 65 of a membrane plug 67, disposed in the opening of the syringe hub 64 (see Figure 14), is penetrated by the inlet 41 end of the needle, which establishes liquid communication with the syringe cavity 66. A pair of tabs 45 extending out from the top of the pressurizing body 31 provide a grip for manually rotating the syringe cartridge 18 into the carriage 70. Relative axial rotation between the syringe assembly 20 and the pressurizing assembly 30 is prevented by disposing the outwardly-extending rims 28 of the syringe wall 21 into longitudinal grooves 37 formed in the inner surface of the pressurizing body 31.

[0100] When the carriage 70 has been moved to and secured in the injection position, the device can also be configured to prevent rotation and removal of the modular syringe from its position in fluid communication with the needle. The tabs 45 extending from the closed end 34 of the pressurizing assembly 30 nest within the oblong recess 17 in the top of the housing 10 to inhibit finger access to the assembly, and to prevent manual rotation. This prevents an

unwanted exposure of a needle that is penetrating the skin from being open at its inlet 42 end to the atmosphere.

[0101] In an alternative method, as shown in Figure 19, the syringe cartridge 18 can be provided in its pressurized configuration, just after the technician has compressed the telescoping pressurizing assembly 30 down onto the syringe assembly 20, and just prior to insertion of the cartridge 18 into the carriage 70. Liquid vaccine may begin to flow from the syringe into the needle 40 in this configuration. The technician immediately inserts the pressurized cartridge 18 into the recess 17 of the carriage 70, and rotates the cartridge 18 to establish liquid communication between the reservoir cavity 66 and the needle 40.

[0102] As shown in Figures 23 and 24, the needle 40 is then inserted into the patient by manual force downward on the syringe cartridge 18 to move it into the housing 10 and toward the base 12, thereby inserting the injection needle 40 into the body and initiating the vaccine injection. The pressing downward of the syringe cartridge 18 also compresses the retraction spring 76, which along with the carriage 70 is retained in an injection position by the retainer heel 86, as shown in Figure 24. Under the relatively

constant force of the plunger spring 33, the vaccine is slowly though constantly expressed out of the syringe and into the targeted body tissue 150. The needle size and force factor of the plunger spring can be configured and designed to cause the vaccine to flow under pressure through the needle within a target volumetric flow rate, to complete the vaccine injection within a prescribed period of time. At the end of the injection, shown in Figure 25, the plunger 24 has moved under the force of spring 33 toward the bottom 22 of the syringe, and has driven substantially all of the vaccine from the reservoir cavity.

[0103] An alternative method of inserting the needle 40 can employ the syringe cartridge 18 as a "plunger" for depressing the needle cartridge to its inserted position, without having the needle inlet 41 penetrate the membrane 65 to the syringe cavity. The syringe cavity 18 can be rested against the bottom of the carriage 70, as shown by the left-side syringe in Figure 31, and pressed downward with having engaged the threads of needle hub 72 and connector 73.

[0104] Once the vaccine injection has been completed, or at any time during the vaccination, the needle can be retracted by engaging a needle retraction means. In the illustrated embodiment of Figure 26, the needle retraction means

comprises one or more release arms 80 and a release button 81. The release arm 80 comprises an upper end 82 shown as a ball having an inward flat surface that is secured within a socket 15 formed in the main body 11. The release arm 80 also comprises a pivot 83 that resides in a detent in the outside of the guide wall 14, and an resilient, flexible elbow portion 84 intermediate the ball end 82 and the pivot 83. A lateral bar 85 on the inside of the release button 81 is disposed proximate the elbow 84. In response to a force on the button 81 that moves the button inward, as shown in Fig. 26, bar 85 causes the release arm 80 to flex inwardly at the elbow 84, causing heel 86 to pivot inwardly and out of engagement with the carriage lower flange 79. As shown in Figure 27, compressed retraction spring 76 then drives the carriage 70 upward from the base 12, and retracts the needle tip 41 completely out of the body and into the housing. After retraction of the needle 40, the syringe cartridge 18 can be grasped and removed by oppositely rotating the cartridge to disengage the threaded connection of the cartridge with the carriage. The cartridge assembly 18 can be inspected to confirm that all the vaccine from the syringe cavity 66 had been injected, and then is disposed. If for

any reason a significant amount of the vaccine remained in the syringe, the syringe cartridge 18 can be reinserted into the carriage and rotated into liquid communication, and the carriage and needle reinserted into the patient to complete the injection.

[0105] The illustrated embodiment in Figures 5, 25 and 27 show the release button 81 having a generally cylindrical shape. The button has a main inner wall 104 and an annular outer wall 101 having an annular periphery that is slightly larger than the annular opening 102 in the housing body 11 in which the button is disposed. The flared outer wall 101 resist movement of the button 81 into the opening 102 until a manual force is applied that is sufficient to bias inward the outer wall 101. As the button 81 is depressed, it biases elbow 84 of the release arm 80. When the force on the button 81 is released, the resilient elbow 84 will spring back against bar 85 to force the button 80 outward to its original position. The button 81 can also provided with a small aperture in its face, through which a small hooked implement can be inserted to pull out the button if it should become lodged inwardly.

[0106] Alternatively, the invention provides that the device 1 can comprise a separable base 92, from which the housing 10

can be removed after completion of the vaccine injection. The separable base 92 typically provides the skin-contacting surface of the base 12. The separable base 92 is configured for securement to the device by a securement means. A separation means provides separation of the separable base 92 from the device. As seen in Figures 2, 27 and 28, the securement means comprises a mechanical engagement, shown as a catch 89 formed on a distal end of a release finger 88 that depends downward from the housing body 11. The distal end of the finger 88 extends through an opening 95 in an inner base member 91. The finger 88 is configured to bias the catch 89 toward and into engagement with a latch 96 formed in the separable base 92, shown in Figure 27. The separable base 92 remains affixed to the housing of the device provided that the catch 89 remains engaged with the latch 96.

[0107] The means for separating the separable base 92 from the permanent base comprises a mechanically-biased member that forces the catch 89 out of engagement with the latch 96. In the illustrated embodiment shown in Figure 27, after the needle 40 and carriage 70 have been retracted, the technician can depress the release button 81

even further, thereby causing a toe 87 on the release arm 80 to pivot into engagement with the release finger 88, and to bias the catch 89 out of engagement with latch 96. With the catch 89 disengaged from latch 96, and with the needle 40 fully retracted, the housing can be safely and easily separated from the separable base 92 for post-injection inspection, and for disposal.

[0108] In an alternative embodiment, the base separating means can comprise other mechanical securements, an adhesive securement, and a magnetic securement of the separable base to the housing of the device. The other mechanical securements could include a mechanical "hook-and-loop" device that can include velcro, a hasp, a frangible joint, and a threaded joint). The magnetic securement can comprise a first magnetic member proximate the upwardly-facing surface of the separable base; and a second magnetic member proximate to the base portion and inside of the housing; wherein first magnetic member and the second magnetic member have a magnetic attraction that secures the removable base to the housing, and wherein the removable base can be manually separated from the base portion of the housing by a manually-applied force that overcomes the force of the magnetic attraction.

[0109] The separable base provides a means for obtaining a secure attachment of the housing of the device to the patient's skin, by providing for outwardly-extending adhesive flaps that are securely affixed to the relatively rigid structure of the separable base. In most circumstances, the separable base that remains behind on the skin of the patient is well tolerated by the patient, and can be removed at any time, since most vaccinations, particularly with very small needle diameters, leave little wounding of the skin. For pre-injection inspection of the device, the separable base 92 can also be removed, by fully depressing the release button 81, prior to installing the vaccine reservoir or the initiating needle insertion. The inner base 91, or a portion thereof, can be made of a transparent thermoplastic material to allow a visual inspection of the needle and the internal assembly prior to use. The separable base 92 can then be easily reaffixed, as shown in Figure 20. The lower surface of the separable base 92 is provided with a wide indent 97 surrounding the opening 95 in the inner base 91. The separable base 92 has a raised flange 94 that registers with the indent 97. Pressing upward on this area assists engaging the catch 89 onto the latch 96 of the separable base 92.

[0110] As shown in Figure 28, the syringe cartridge 18 can first be removed from the attached housing 10, before the housing is removed from the separable base; or, the housing with the syringe cartridge can be removed from the separable base as a unit, and then the syringe cartridge can be removed.

[0111] The device can also comprise a means for preventing deployment of the needle through the opening in the base of the housing, particularly after the needle has been inside the skin of a person. A typically means for preventing needle deployment comprises a sliding or rotating plate disposed in the base that can moved between a first position where the needle opening in the base is not covered by the plate, and a second position wherein the plate covers the opening. In the embodiment illustrated in Figs. 36–38, a rotating plate 131 is disposed in an annular recess 130 on the annular flange 94 of the inner base 91. The recess 130 and plate 131 have a center that is positioned off the centerline 100, though they cover the needle opening 13 in the base 12. The plate 131 has an opening 136 disposed between the center of the plate and its periphery. The plate 131 is rotated to a first deployment position wherein the plate opening 136 exposes the

opening 13, and to a second blocking position wherein the plate opening 136 exposes the opening 13, and prevents deployment of the needle 40. The plate is movable between the first and second positions by a knob 132 that is attached to the plate by a stem 133. The stem is disposed within arc-shaped stem slot 134. The knob 132 moves along a knob recess 135 formed in the inner surface of the removable base 92, and that lies below the knob slot 134. The knob retains the plate in position, and can be manipulated by finger to move the plate between its first and second positions. Prior to injection, the technician can remove the removable base plate and manipulate the knob 131 to move the plate 131 to its deployment position. After the device is removed from the skin following the injection, and the separable base 92 has been removed, the exposed knob 13 can be manipulated to move the plate 131 to its blocking position. This physically closes the opening 13 to ensure that the needle 40 can not be redeployed accidentally and cause an undesired stick.

[0112] In a further embodiment of the present invention, a device can have a plurality of injection needles and vaccine reservoirs disposed within the housing. The device can

provide for injecting at least two vaccines to a patient. As shown in Figures 29–31, a device 1 can comprise a housing 10 and base 12 for two needle carriages 70 and two injection needles 40, which can be configured to be separately and independently manipulated for insertion, injection and retraction, as described herein above.

[0113] Alternatively, the two needle carriages and needles can be configured for simultaneous insertion, injection, and retraction using shared elements, including a shared, dual-recess needle carriage 70, and a dual pressurizing assembly 30.

[0114] If only one vaccine will be administered, there is a potential for the patient, during the injection procedure, to pick at and possibly poke a finger through the seal 105 that is initially positioned over the cavity recess 71. To prevent this, the seal 105 can be affixed to a cylindrical member 106 that partly supports the underside of the seal 105 layer, as shown in Figures 3 and 3A. Alternative, the seal can be removed and replaced with a "dummy" plunger that has the upper appearance of the active syringe cartridge, but which fits securely in the opening in the housing above the carriage to block any attempt to depress the carriage.

[0115] A further embodiment of the invention can comprise a means of indicating the extent of vaccine dispensed from the reservoir. The indication means can comprise a visual means that allows personnel to actually view the remaining contents of the reservoir. An embodiment of a visual indication means can comprise a transparent section positioned in a portion of the housing adjacent the reservoir, to view the reservoir. Alternatively, the housing can comprise a door or panel that can be opened to permit inspection. Further, the reservoir can be provided with a corresponding transparent portion to permit the medical personnel to see the medication contained within the reservoir. The transparent portion can include a portion of the base or a portion of the housing, or both. The transparent portion can be a small area relative to the total surface area of the housing body, or can be a significant portion of the housing body surface. In a typical embodiment, the transparent portion is positioned on one side of the housing body that, when applied to the patient's arm, can face away for the patient's line of sight. This allows the medical technician to see through the transparent portion, but provides no indication to the patient, typically a small child, that the inside of the device contains some-

thing interesting that might arouse the patient's curiosity.

[0116] The indication means can also comprise a signal means that signals the end or the approaching end of medication dispensing. A signal means can comprise a mechanical or electrical switch that is activated by the plunger member as the last remaining contents of the reservoir is dispensed. The signal can be a flag, a pop-out tab, an illuminated light, or any other well known signal.

[0117] Another embodiment of the invention can comprise a covering or disguise configured for attachment or placement over the injection device either to provide the device with a pleasurable impression, or to direct the patient's attention away from the device. The covering can be formed as a cartoon character, a zoo animal, or the like. In this way, much of the patient's fear that might be caused by the sight of the device can be alleviated.

[0118] In another embodiment of the invention, the housing of the device can be colored coded or have a colored indicator or marking that identifies the particular type or quantity of medication contained within the reservoir. For example, for one certain medication the outer casing may be blue in color. The device can also display various warnings, such as a precaution to avoid needle stick and pos-

sible side effects to the medication. The device can also comprise a removable label comprising information about the vaccine to be administered (such as the type of vaccine or medicament, the manufacturer and lot number, and volume), which can be placed into a medical record or patient chart.

[0119] Another embodiment of the invention, shown in the figures, is an improved injection device for self-administering a vaccine injection that does not provide the patient with any convenient fingerhold to grasp the device for jostling or removing the device from the skin during the injection procedure. A preferred design of the device will include an outer surface that has not sharp edges or deep groove with which the patient can get a fingerhold. Preferably, the housing and the base is constructed of a thermoplastic material that has a non-grip or non-sticky surface, and is preferably a resilient material that can flex but not deform in shape. A matte finish on the outside surface can make the housing difficult to grasp, except when properly grasped by a medical technician by its release buttons. Typically, the indentures and grooves in the housing, and including the base, have a breath not greater than 3 mm, more typically not greater

than 1 mm. Typically, external edges can be rounded, maintaining an edge radius of about at least 1 mm, more typically of about at least 3 mm.

[0120] While specific embodiments of the apparatus and method of the present invention have been described, it will be apparent to those skilled in the art that various modifications thereto can be made without departing from the spirit and scope of the present invention as defined in the appended claims.

Claims

- [c1] 1. A manually-powered injection device for painless inter-muscular injection of a vaccine, comprising:
- a) a housing having a base for semi-permanent attachment to the skin of a patient,
 - b) an injection needle disposed substantially perpendicular to the base and within the housing, the needle having an injection end, and configured for axial movement between a first position wherein the injection end is within the housing and a second position wherein the injection end extends outwardly from the base to a distance sufficient for intramuscular insertion thereof, the injection needle having an outside diameter greater than 0.20 mm and less than about 0.38 mm,
 - c) a reservoir containing a vaccine,
 - d) a means for liquid communication between the reservoir and the injection needle,
 - e) a manually-powered means for inserting the injection needle to its second position, and
 - f) a means for injecting the vaccine from the reservoir to the injection end of the needle.
- [c2] 2. The injection device of Claim 1 wherein the means for

injecting is a manually-powered means.

- [c3] 3. The injection device of Claim 1, further comprising a needle insertion securement for retaining the inserted needle in its second position while injecting the vaccine.
- [c4] 4. The injection device of Claim 1 further comprising a means for retracting the injection needle, whereby the injection end of the needle is retracted from its second position to a third position wherein the injection end is within the housing.
- [c5] 5. The injection device of Claim 1 wherein the manually-powered means comprises a needle carriage to which the injection needle is affixed, the needle carriage being configured for axial movement in response to a manual force applied by a medical technician between a first position associate with the first position of the injection needle, and a second position associated with the second position of the injection needle.
- [c6] 6. The injection device according to Claim 5 further comprising an implement for use in applying the manual force to the needle carriage.
- [c7] 7. The injection device according to Claim 6 wherein the implement comprises a plunger having a first end that is configured to engage the needle carriage, and a second

end to which is applied the manual force.

- [c8] 8. The injection device according to Claim 1, further comprising a needle insertion securement for engaging and retaining the needle carriage in its second position while injecting the vaccine.
- [c9] 9. The injection device according to Claim 1, further comprising a retracting means comprising a means for disengaging the needle insertion securement from the needle carriage, and a power means for moving the needle carriage from its second position to a third position associated with a third position of the injection needle wherein the injection end is within the housing, whereby when the needle carriage is not secured in its second position, the retracting power means moves the needle carriage to its third position.

[INJECTION DEVICE FOR ADMINISTERING A VACCINE]

Abstract

A manually-powered injection device that self-administers a painless vaccine injections. The injection device can provide a method for substantially painless injections of vaccine and other medication into a patient that does not require the use of an anesthetic, that does not require the medical personnel to spend a substantial amount of time performing the injection procedure, that is relatively simple and inexpensive to perform and operate, and that provides a relatively high degree of safety for both the medical personnel and for the patient. The injection needle can have an outside diameter greater than 0.20 mm and less than about 0.38 mm. The medicament can be injected painlessly through the needle and into the patient at a substantially constant volumetric flow rate of about 0.05 $\mu\text{L/s}$ to about 50 $\mu\text{L/s}$. The injection device is configured for easy handling, and is manually-powered by the use of the hand or fingers of the medical technician.

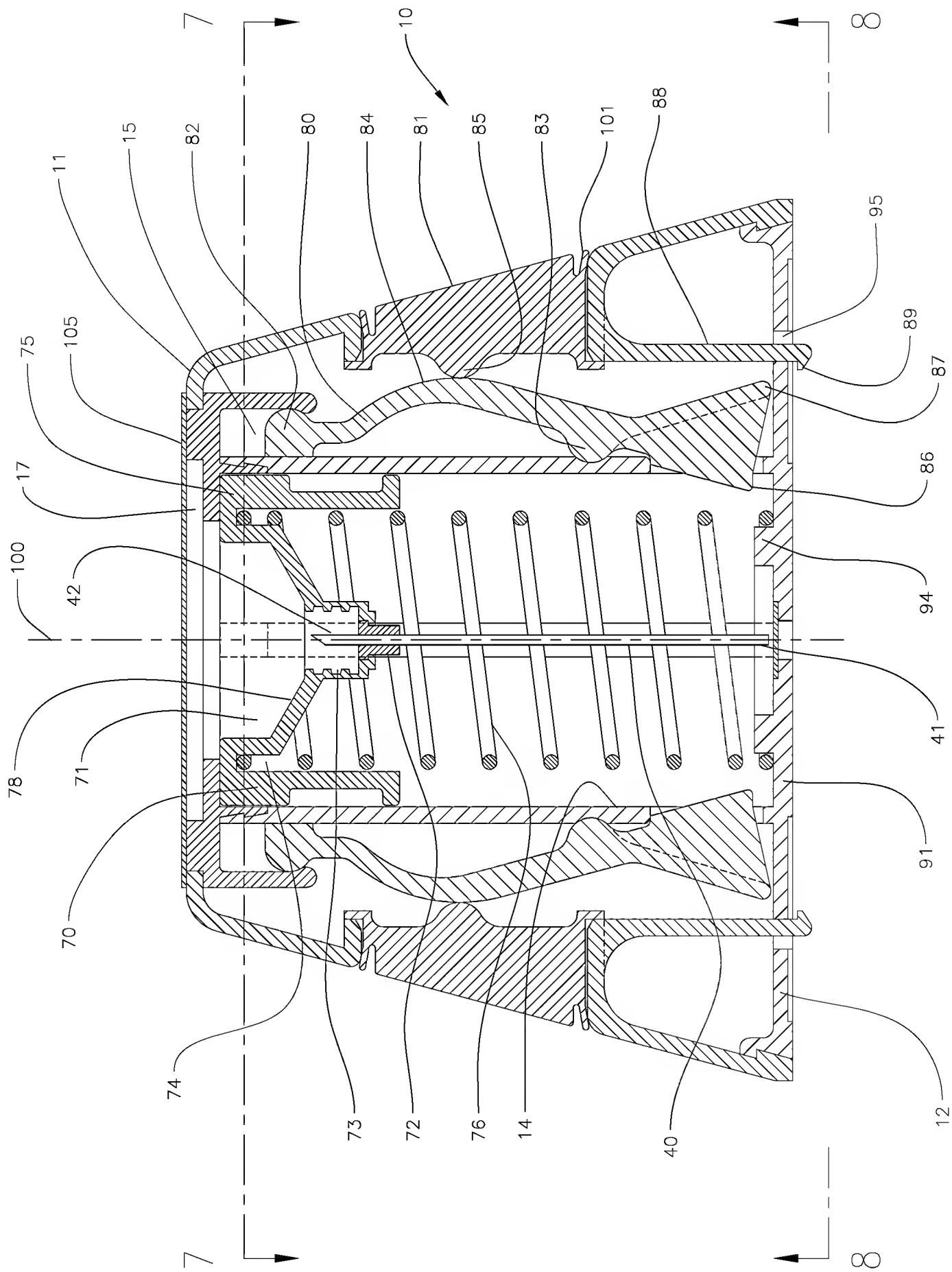


Fig. 1

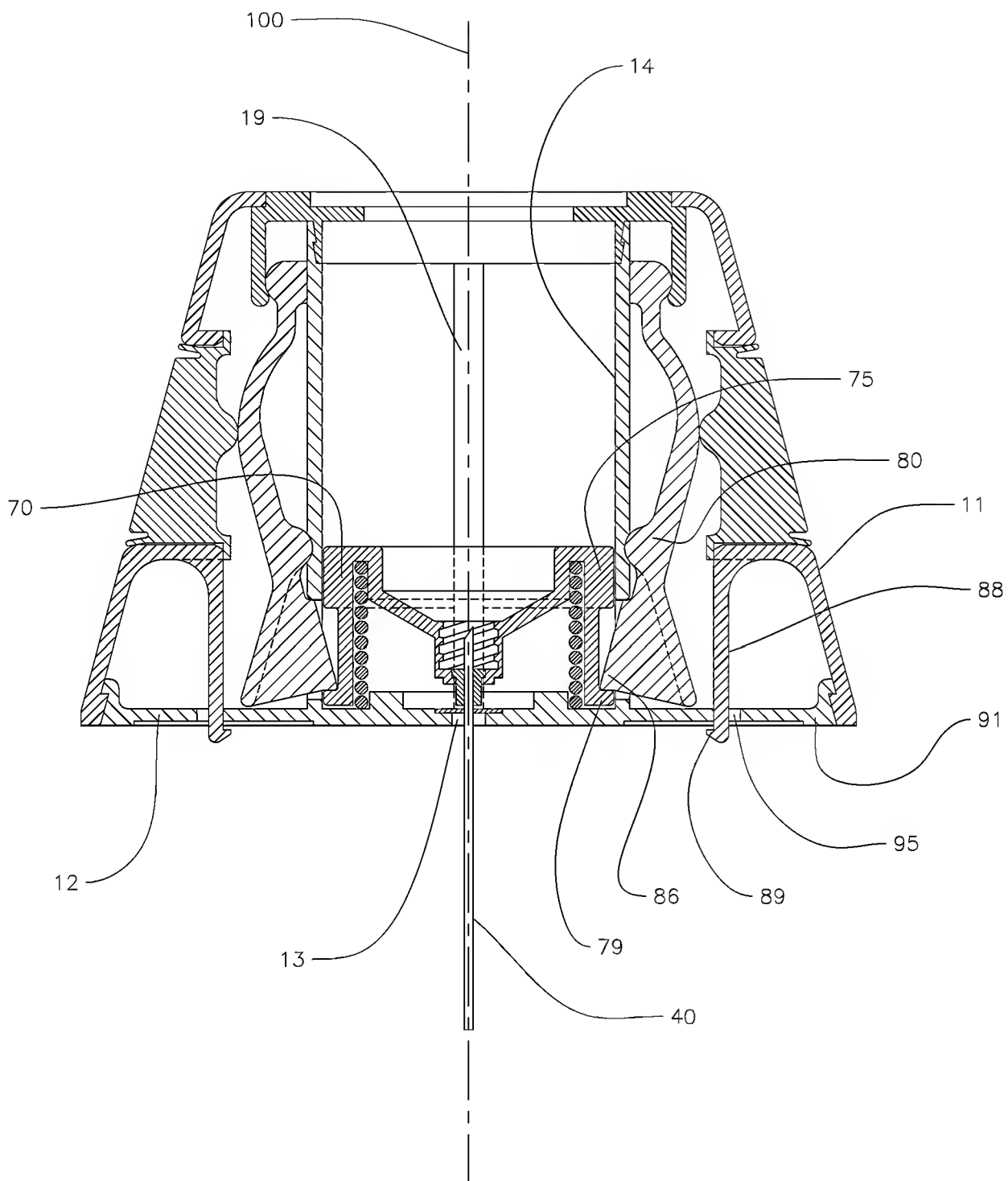
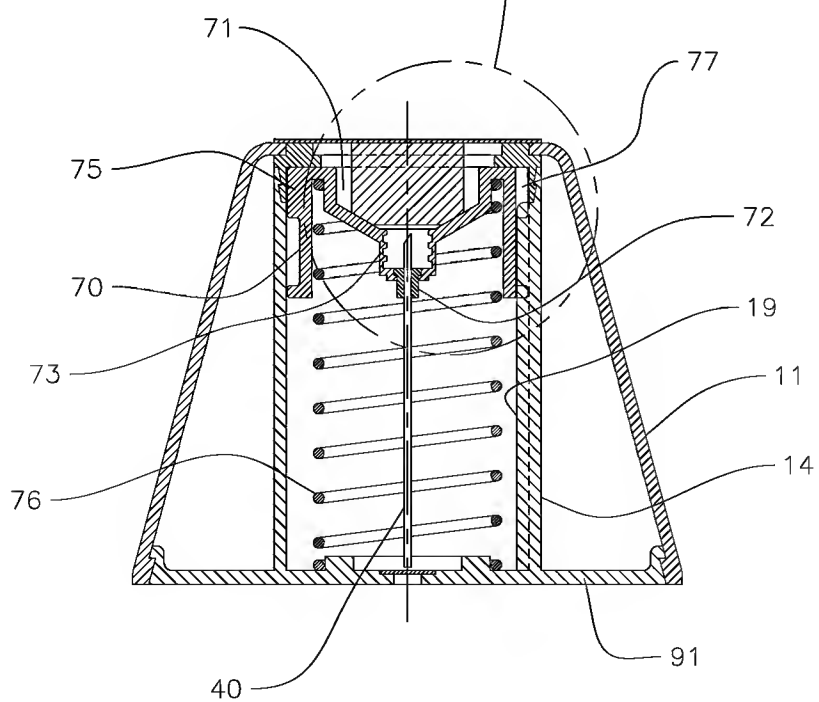
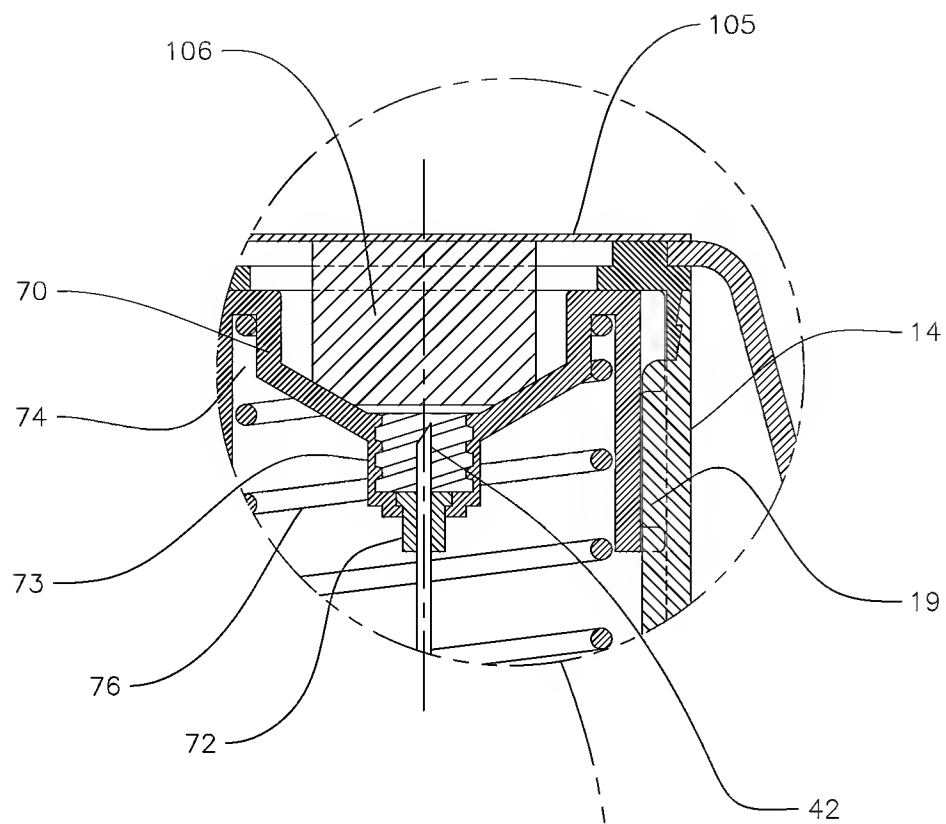


Fig. 2



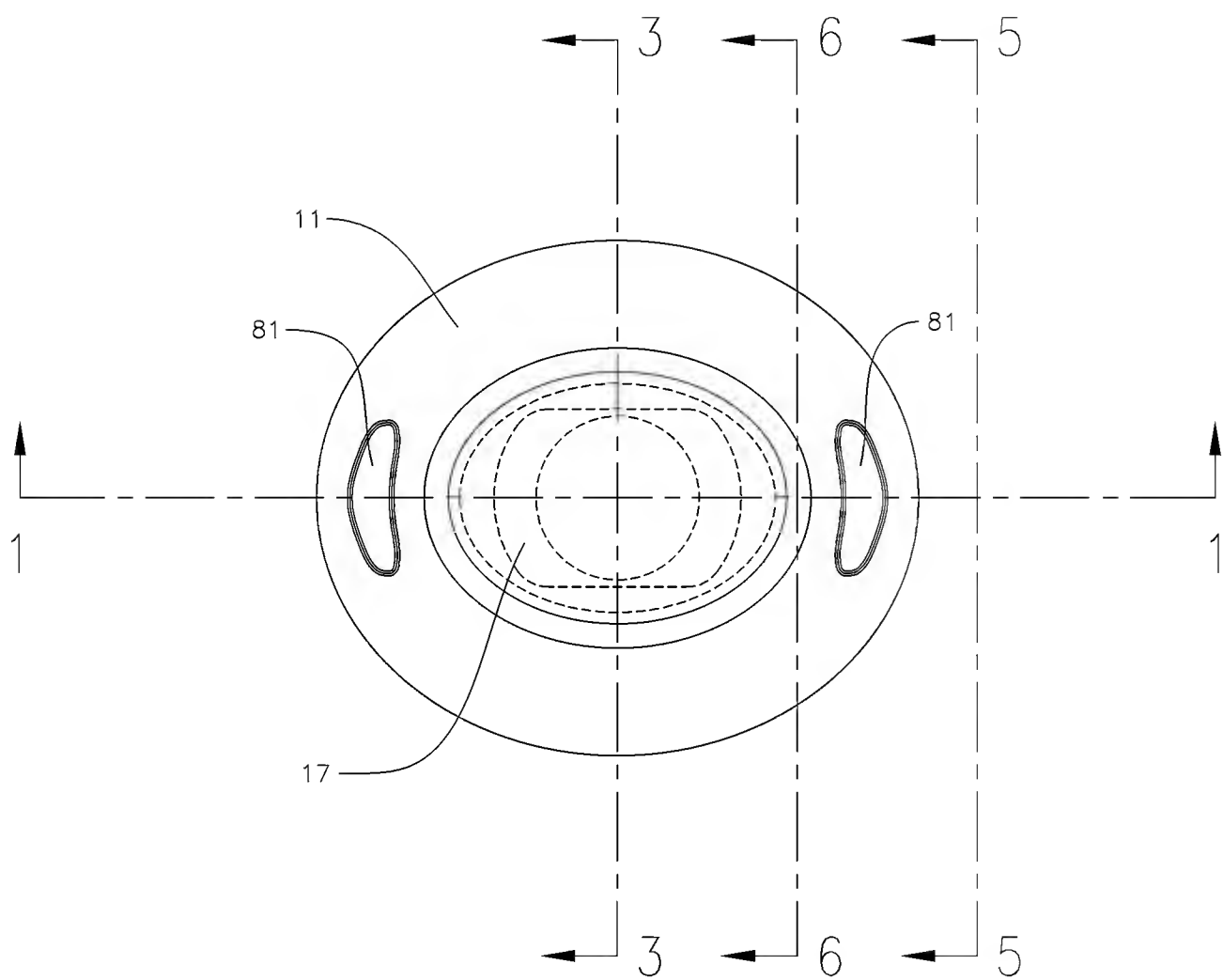


Fig. 4

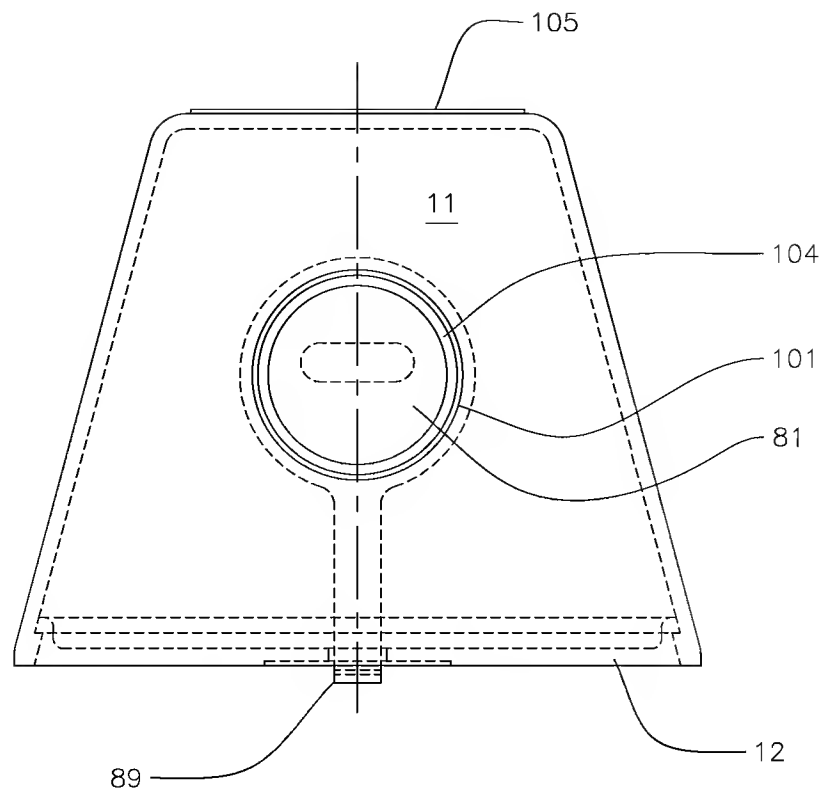


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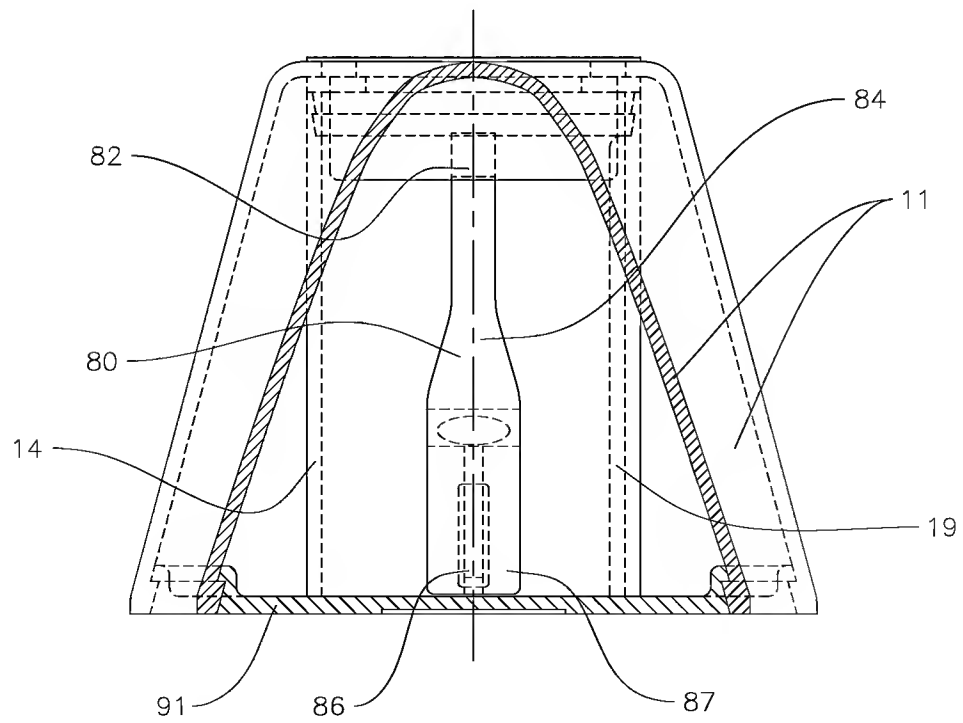


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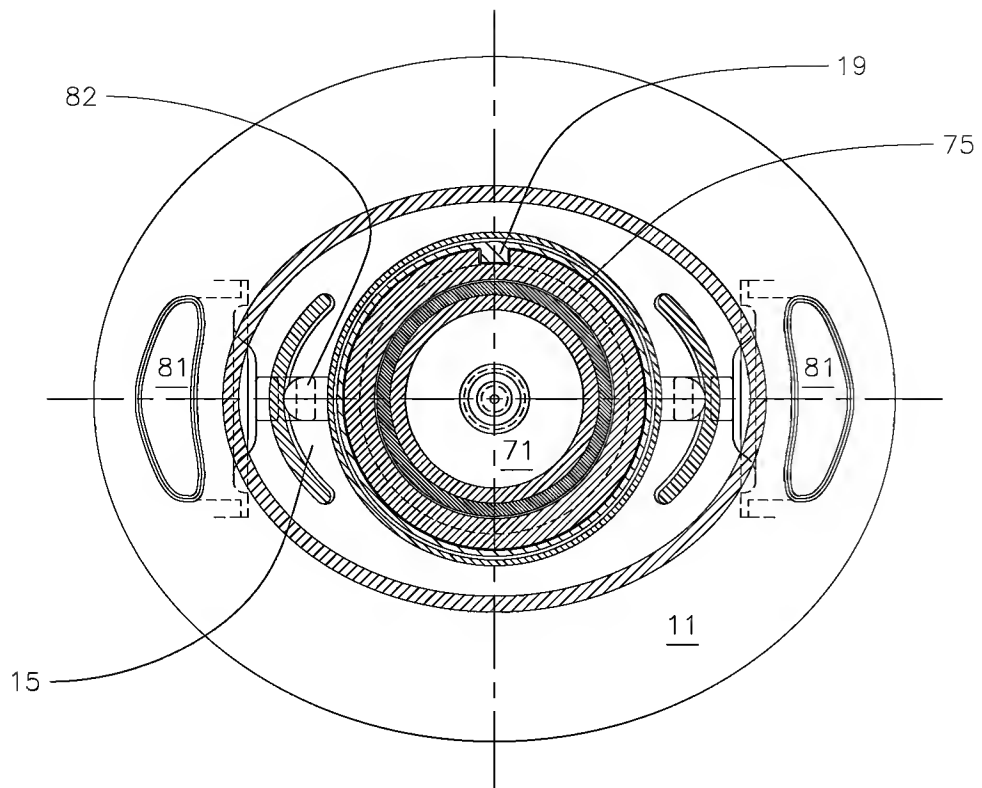


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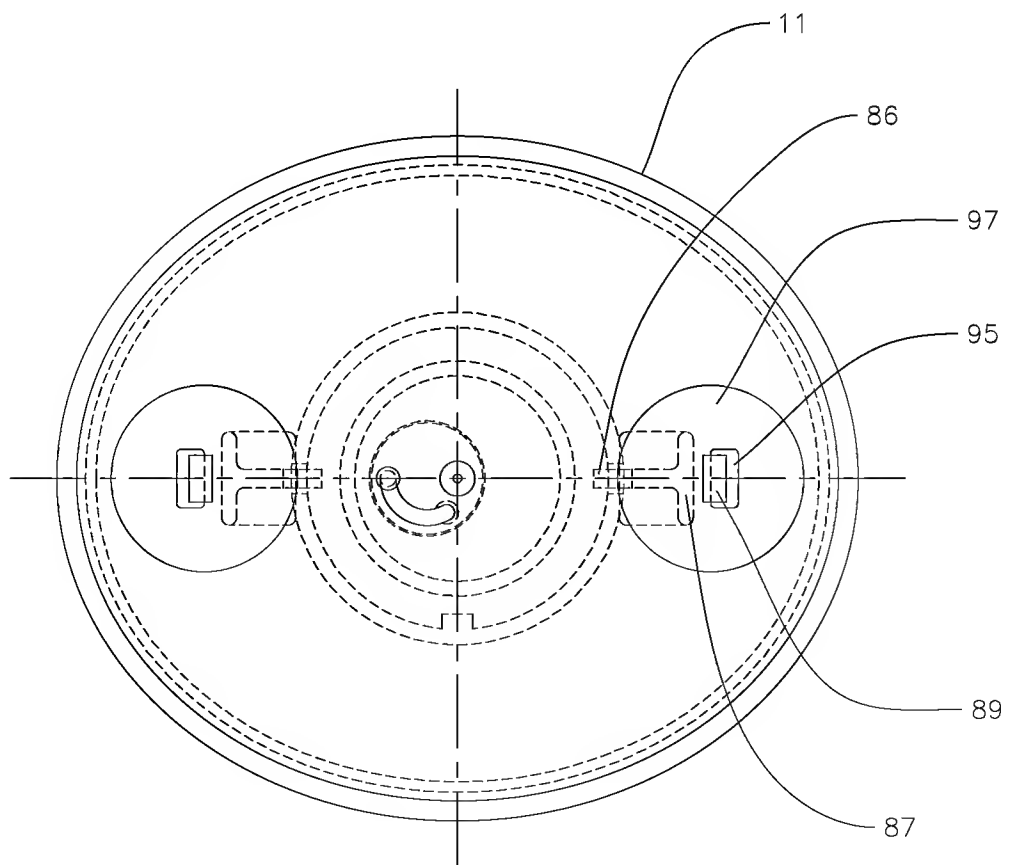


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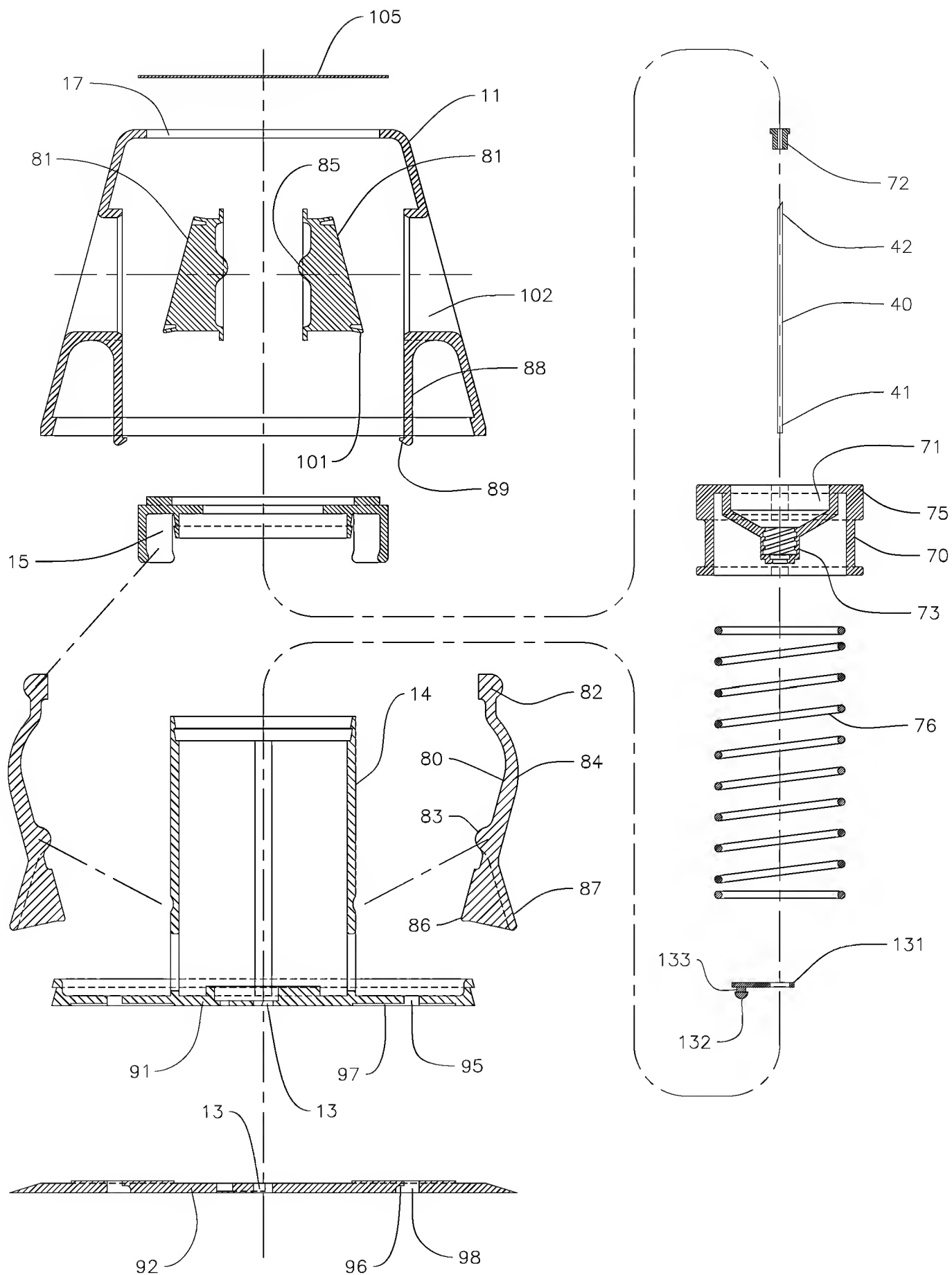


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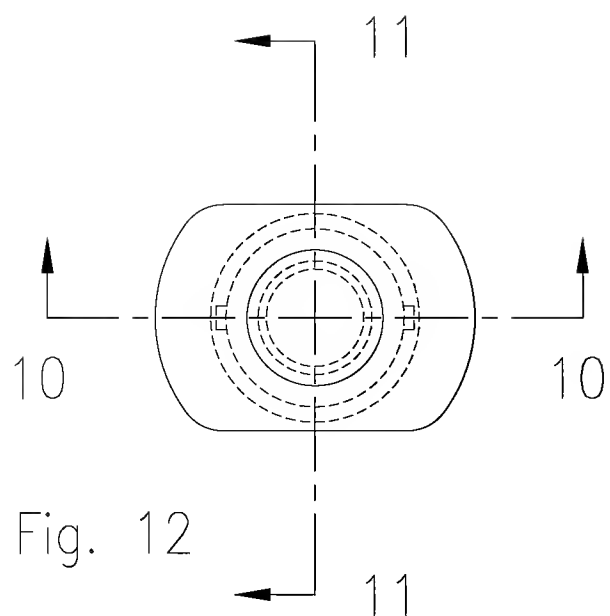


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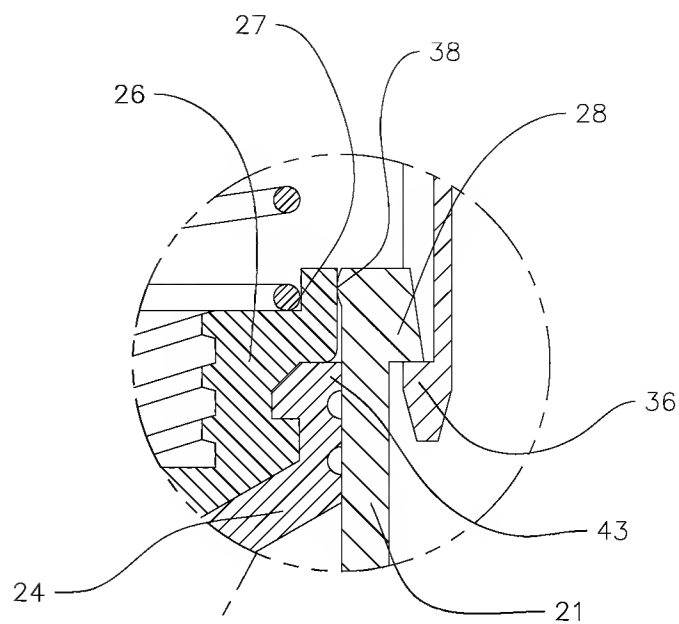


Fig. 13

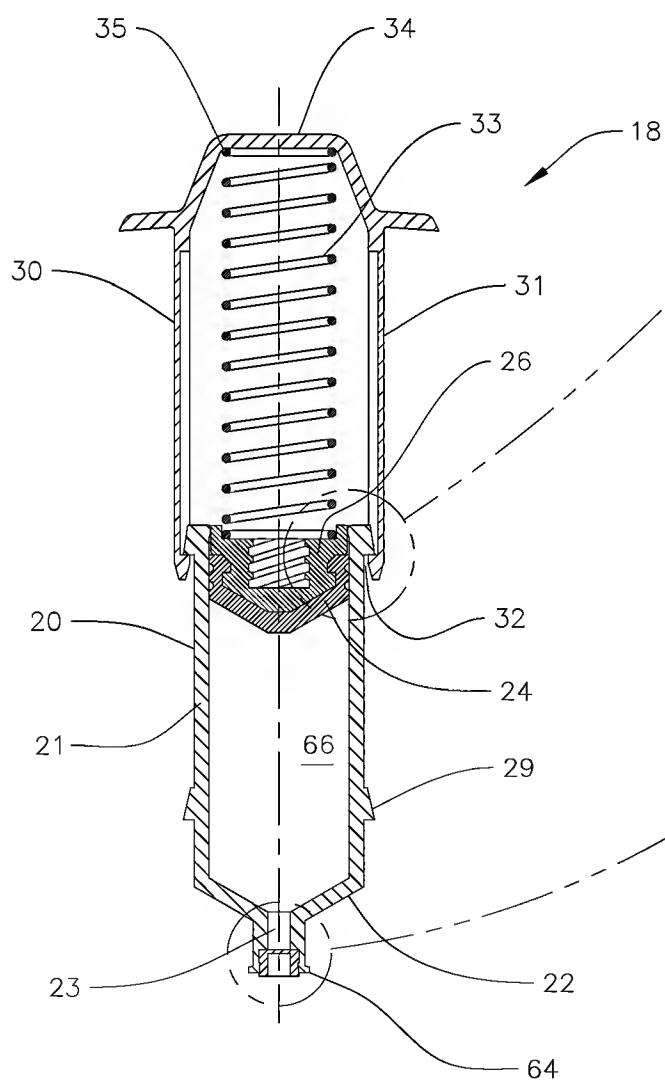


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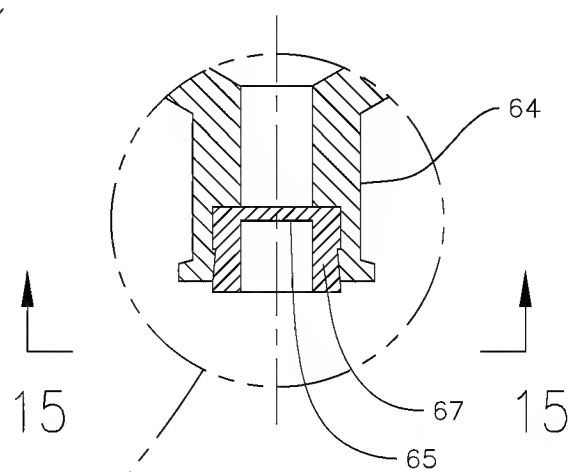


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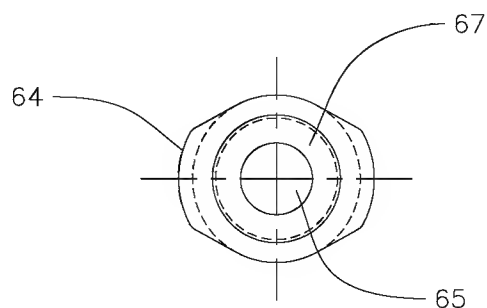


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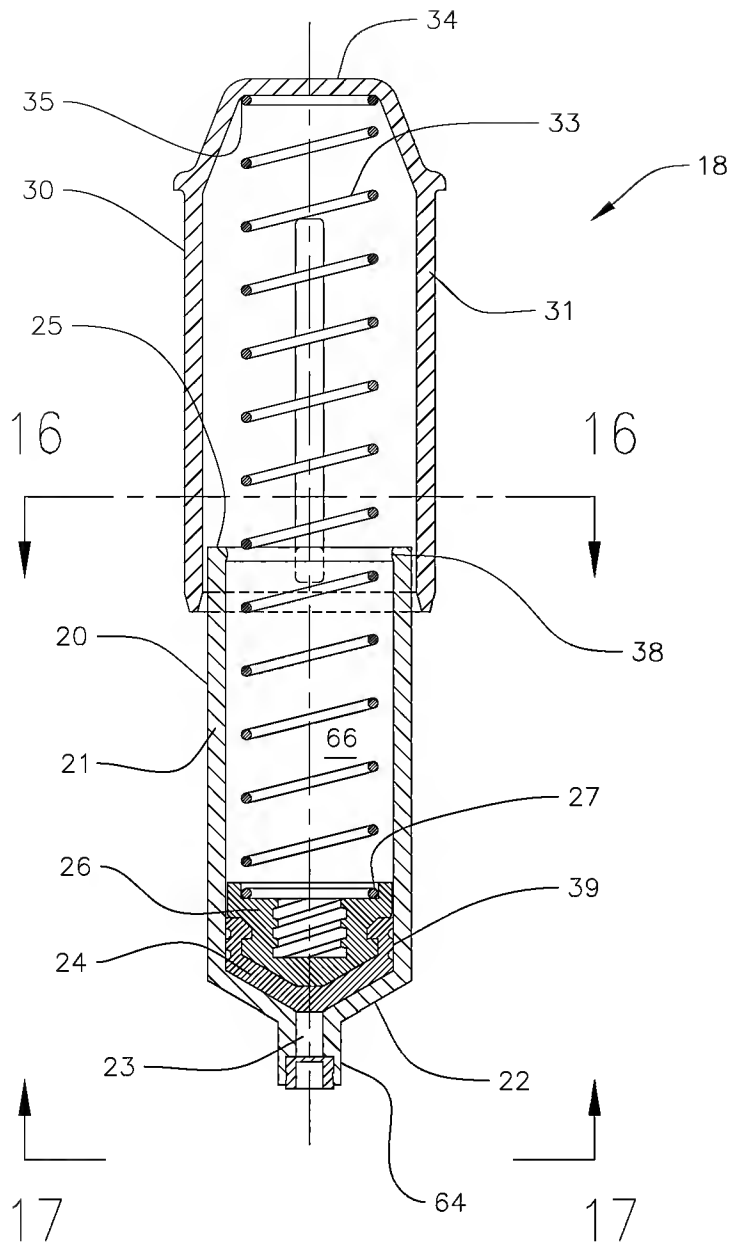


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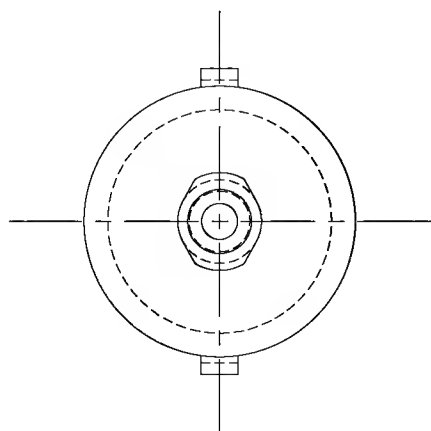


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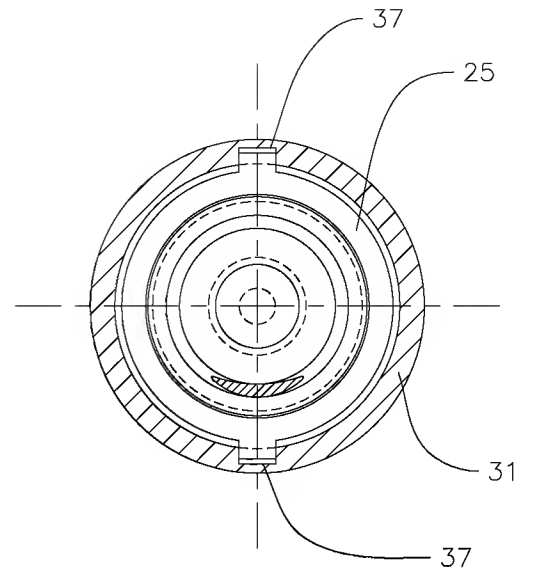


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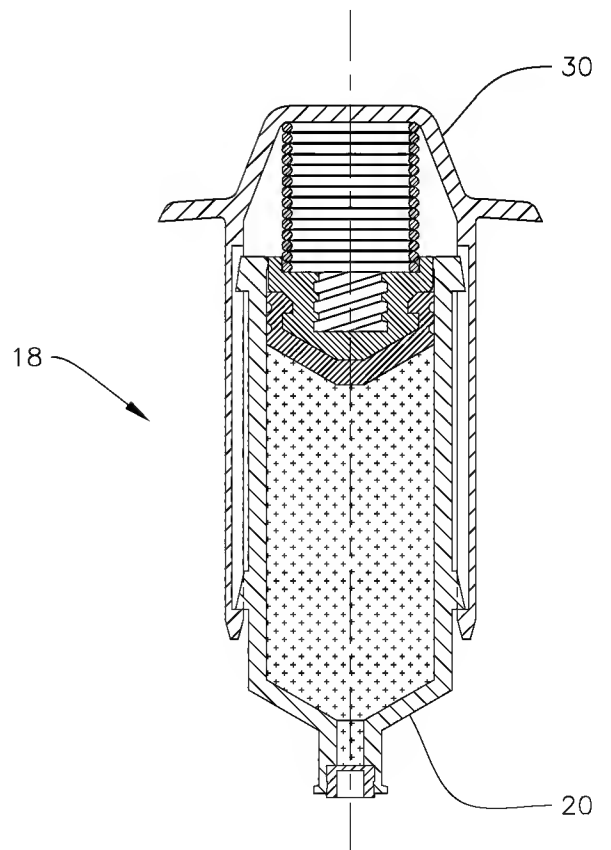


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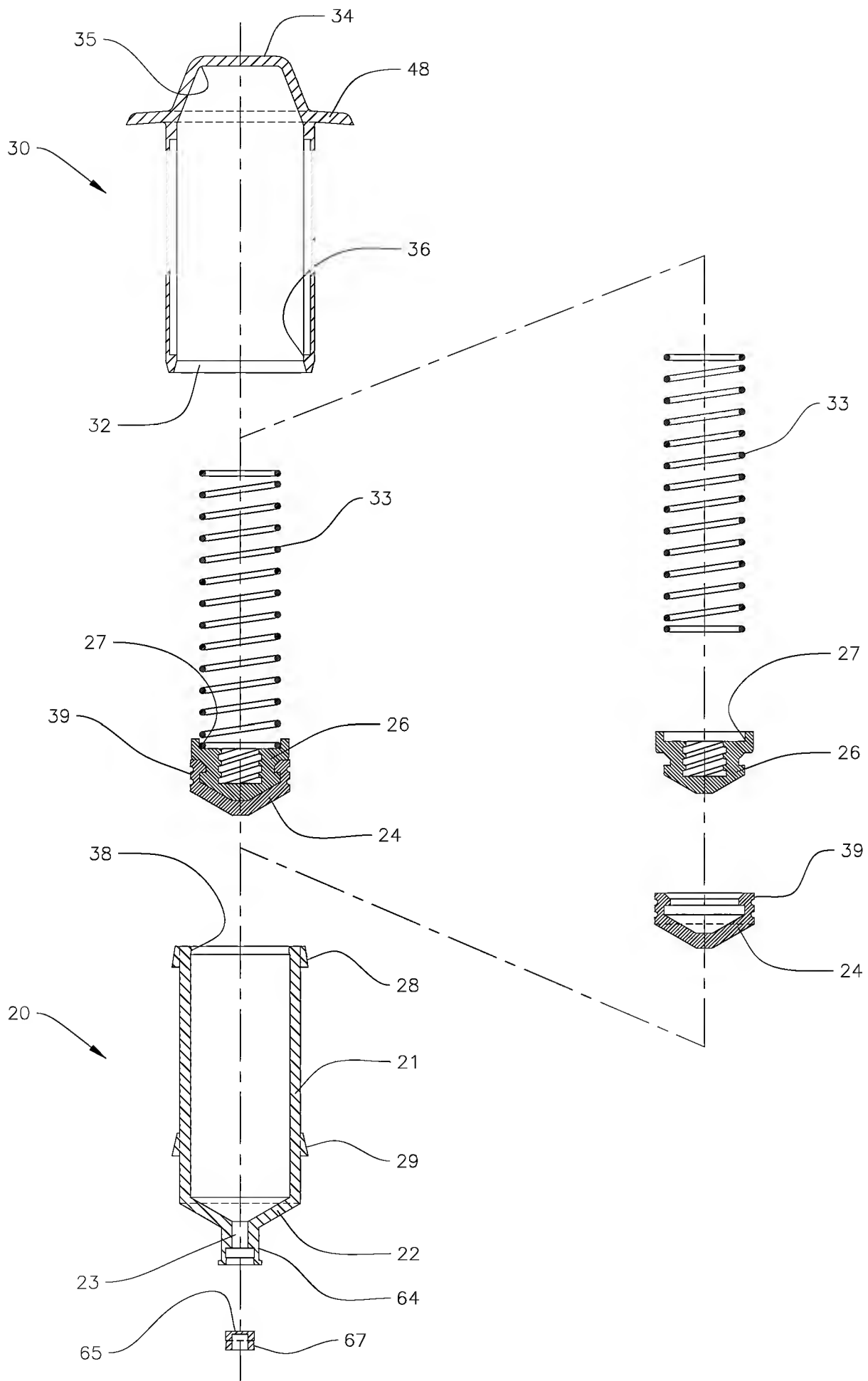


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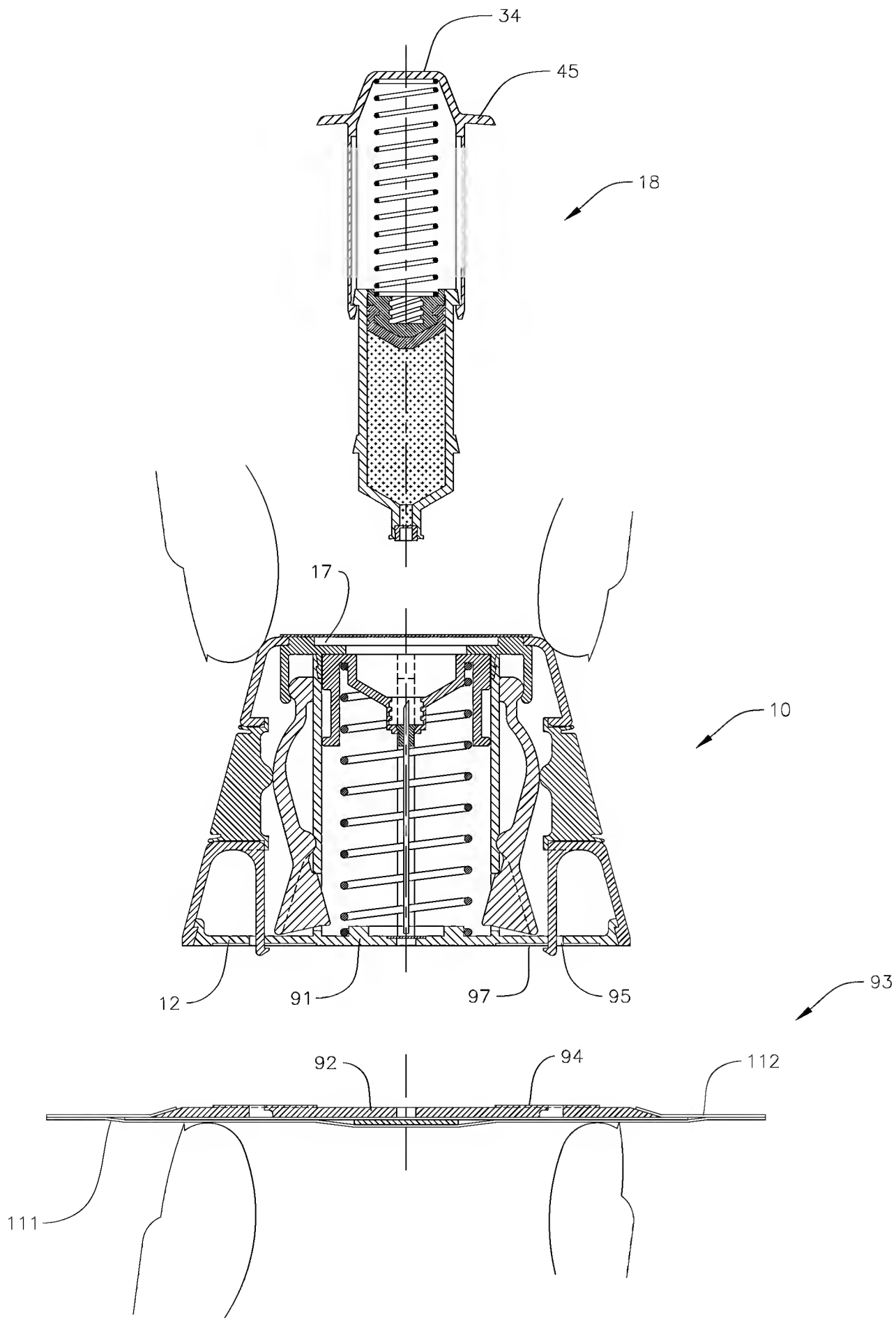


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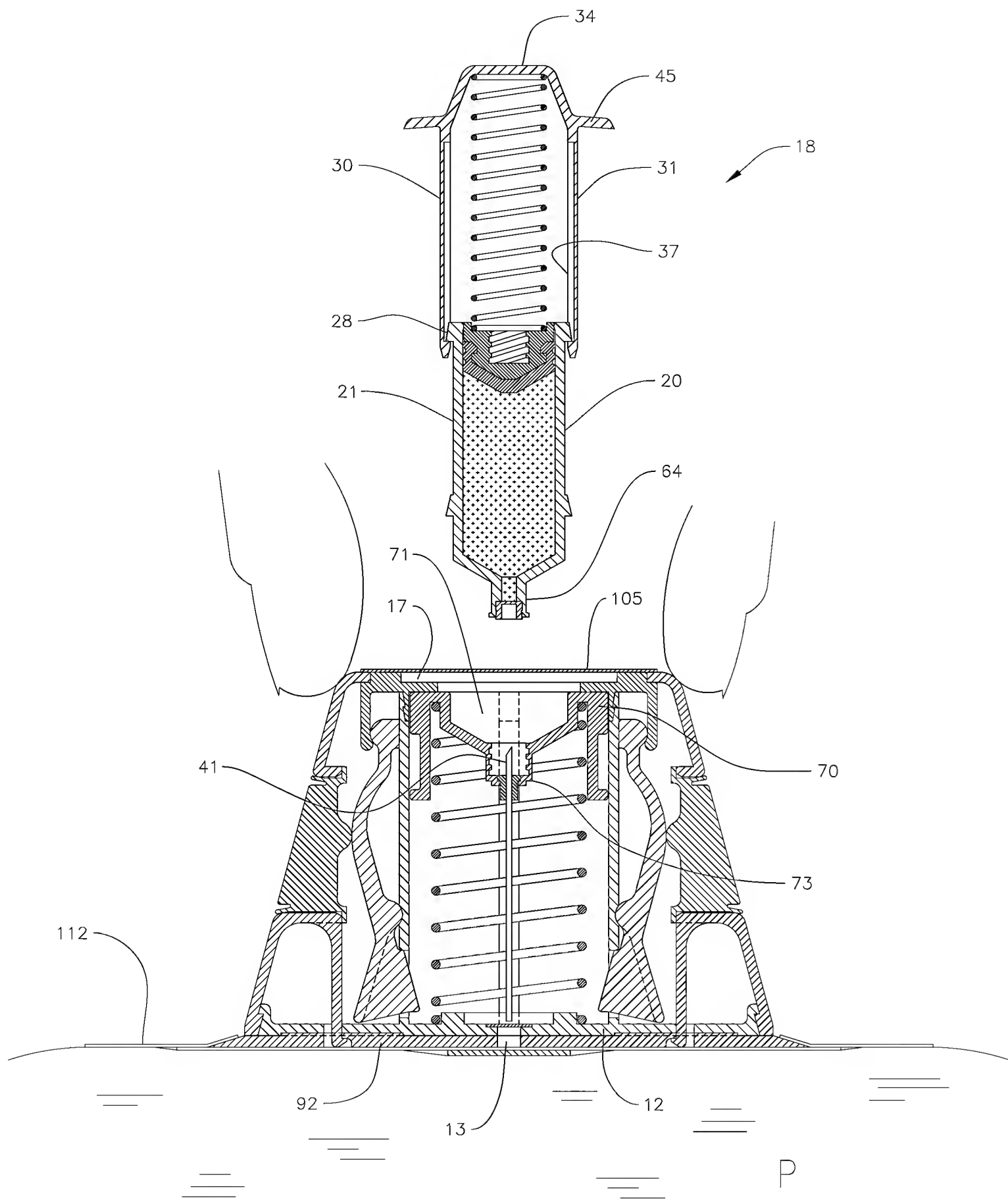


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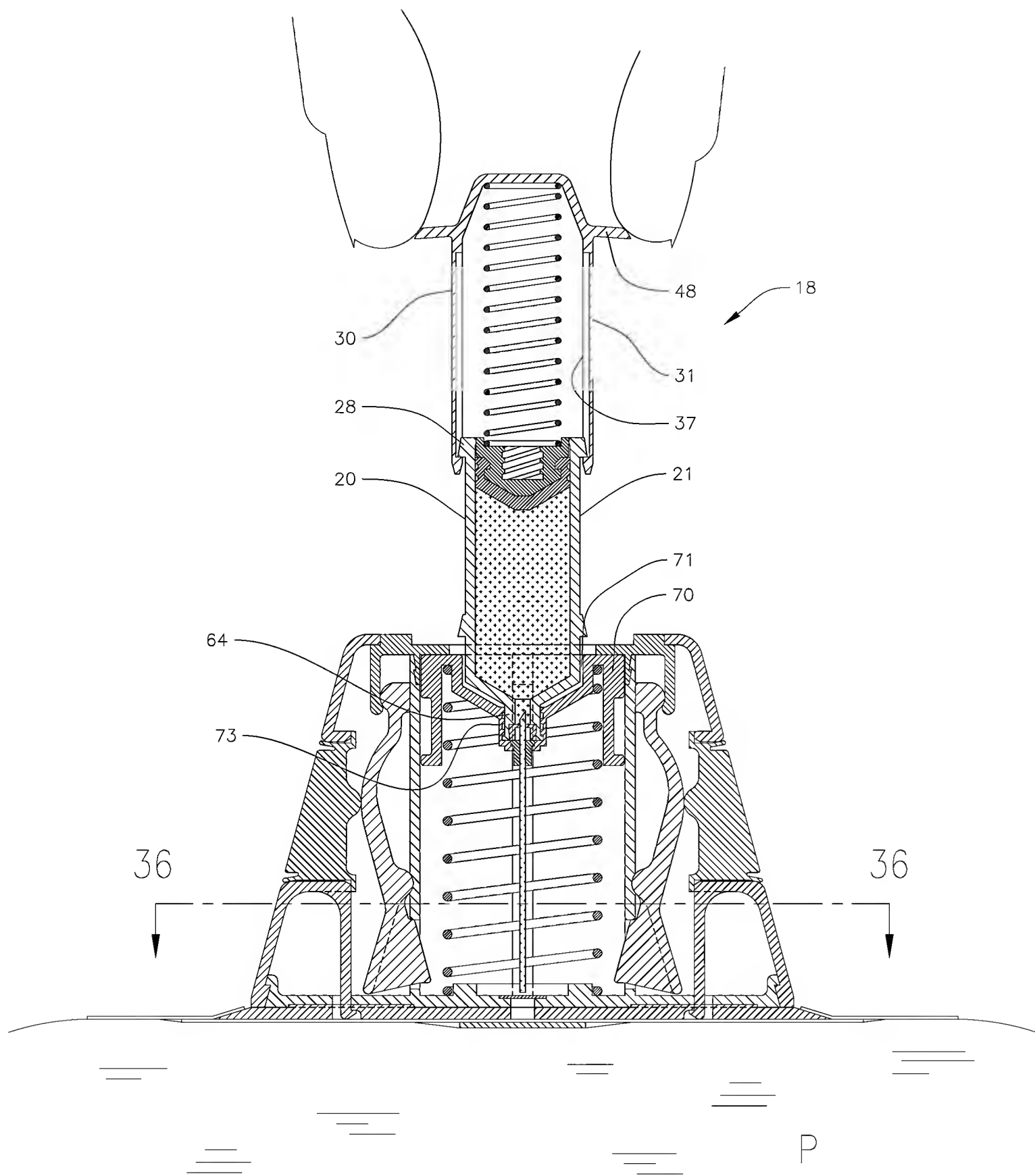


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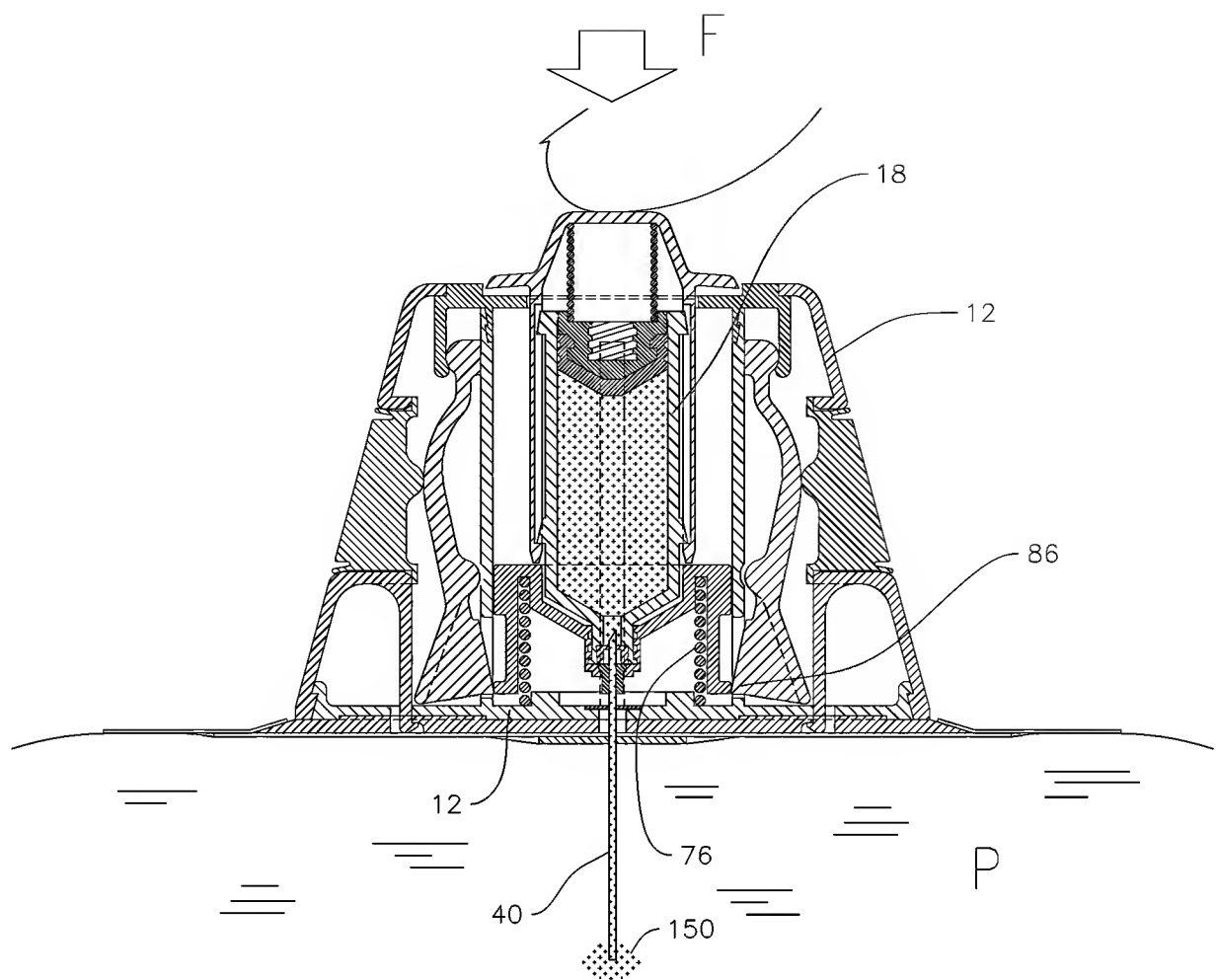


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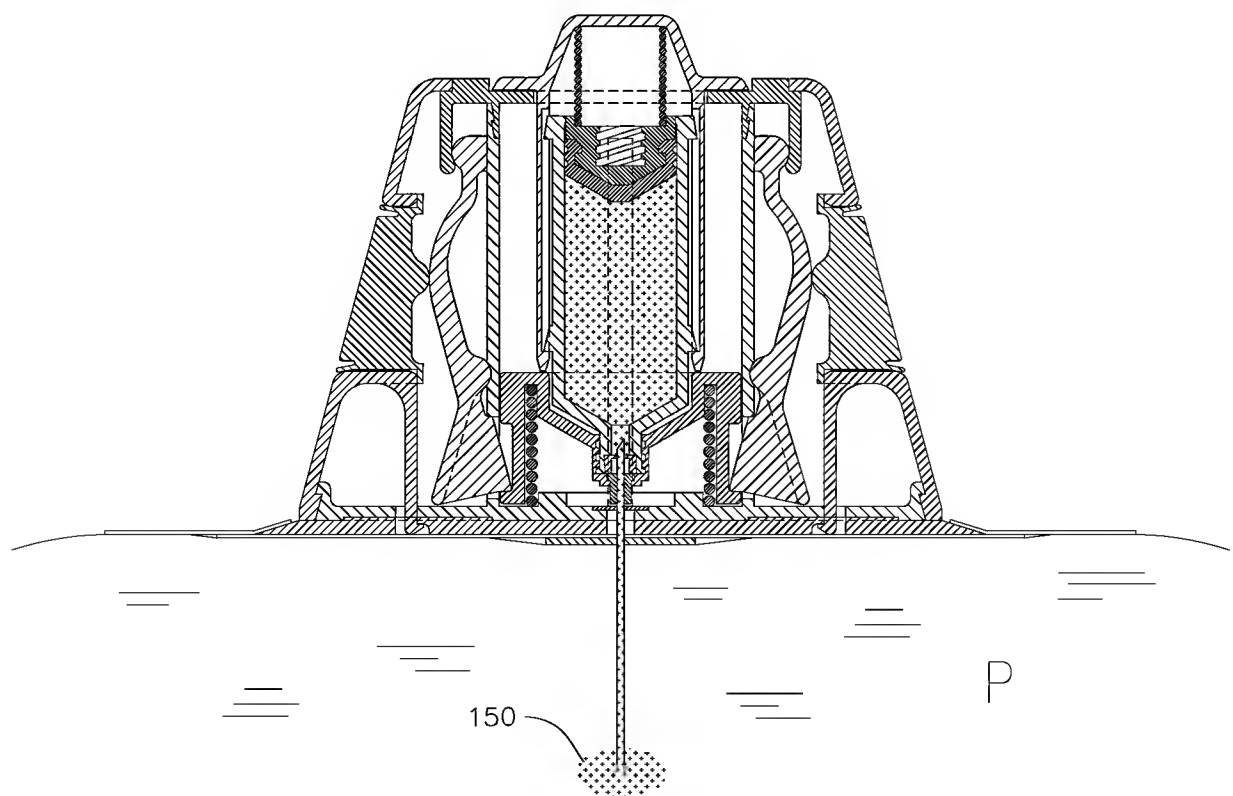


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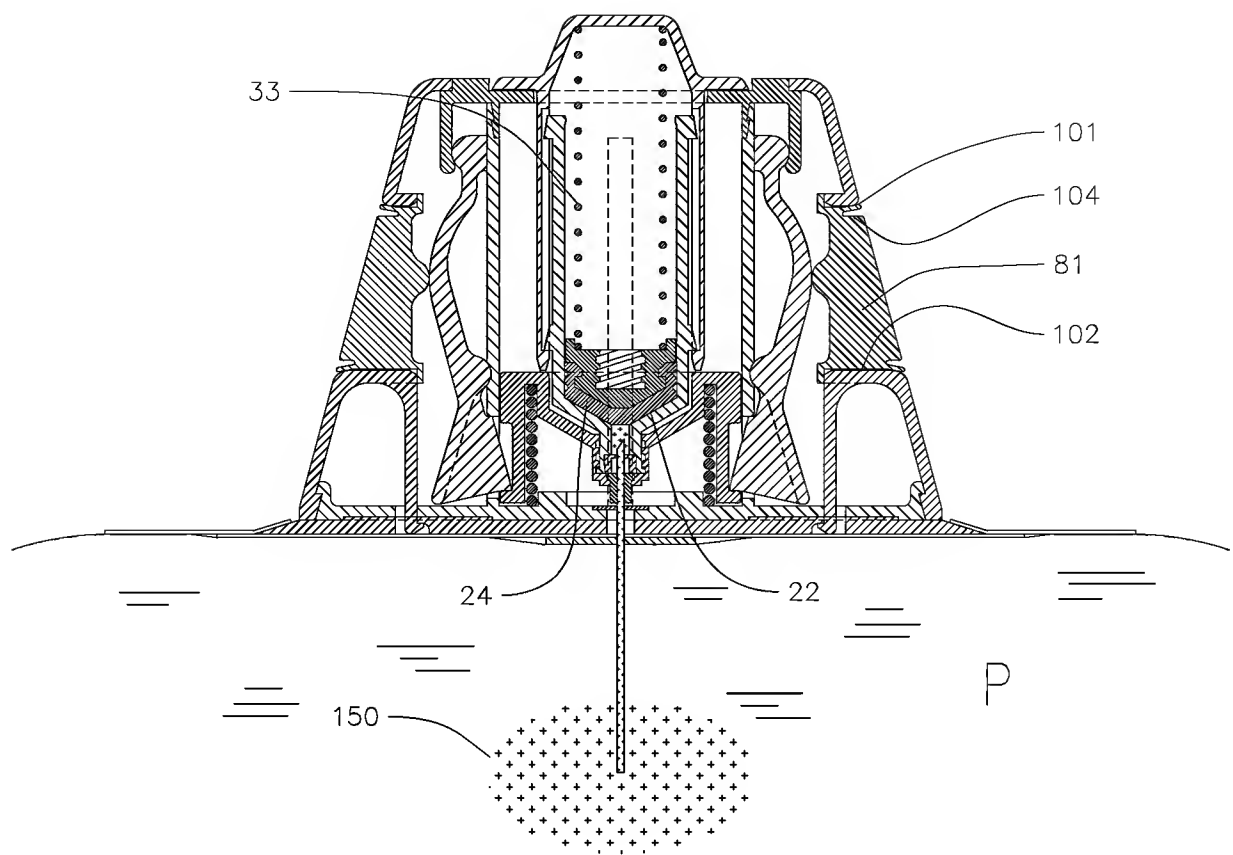


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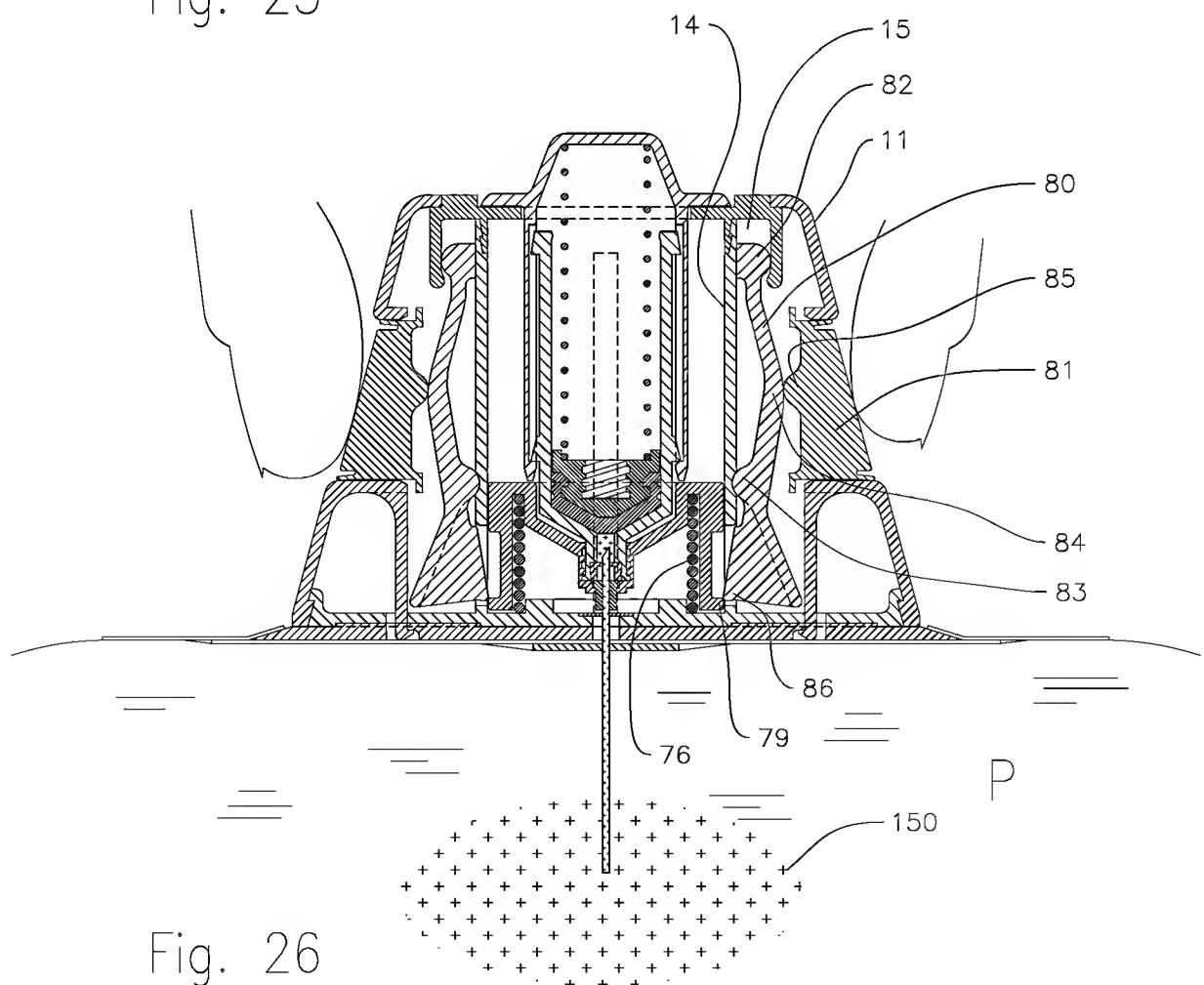


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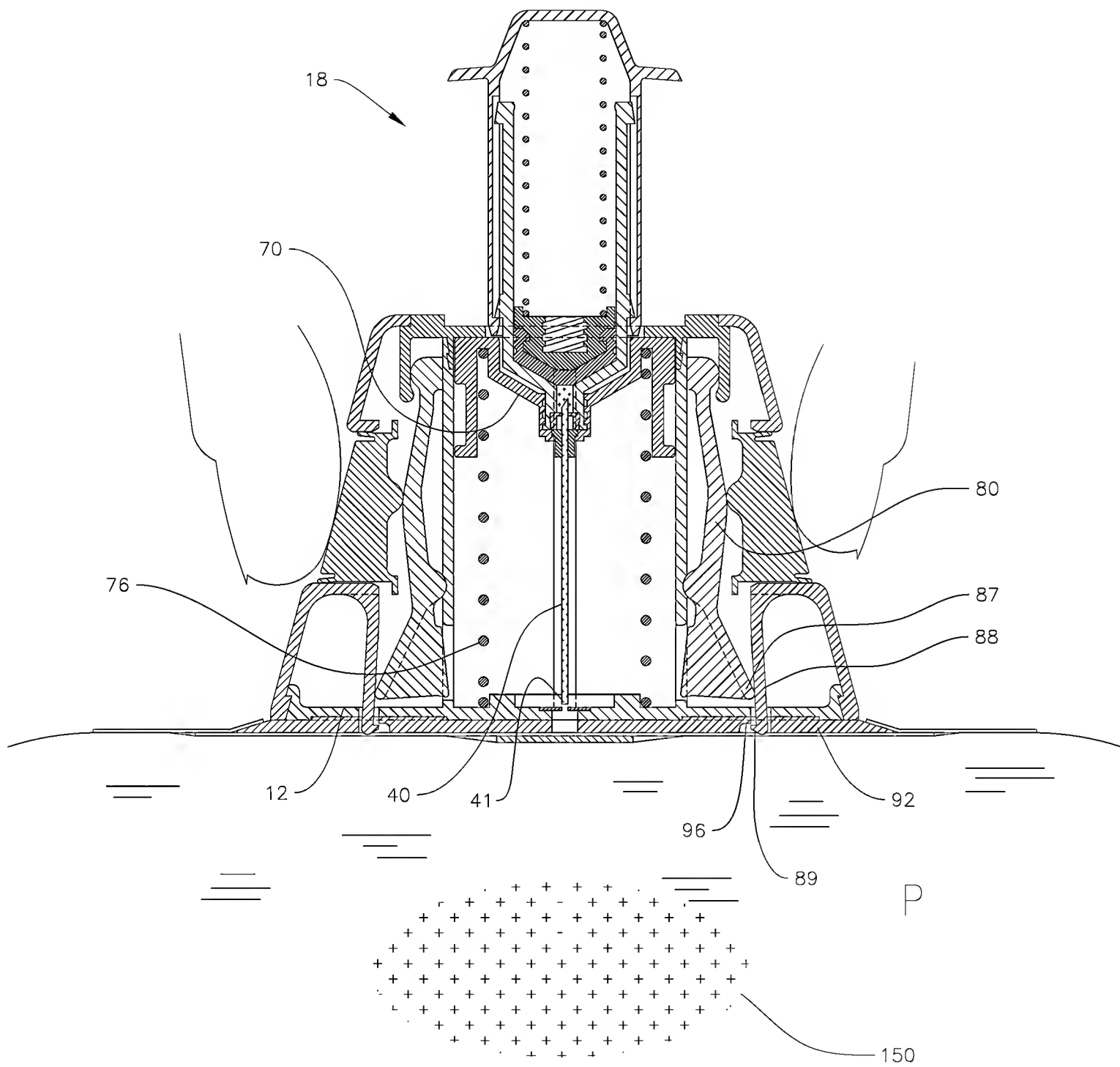


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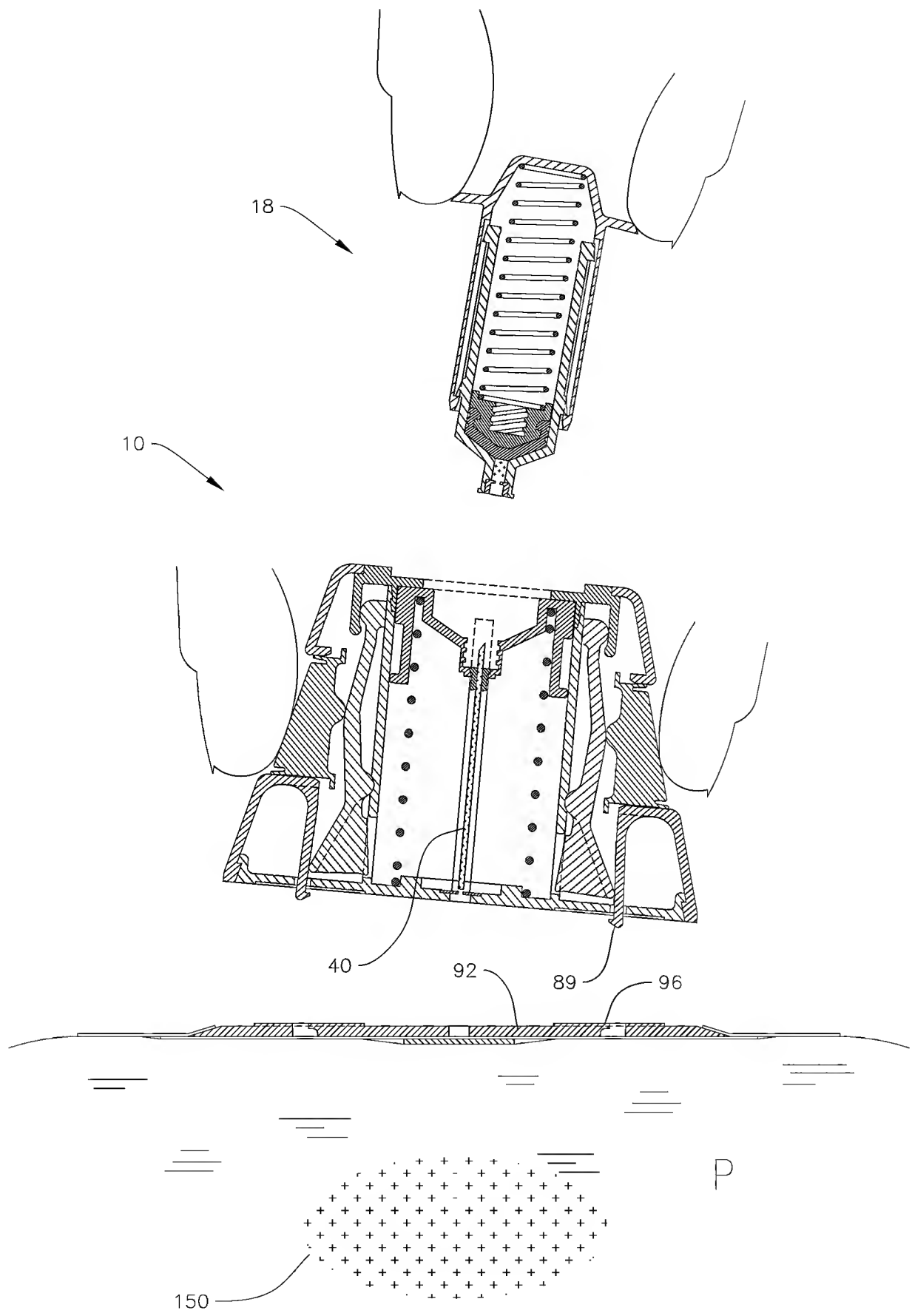


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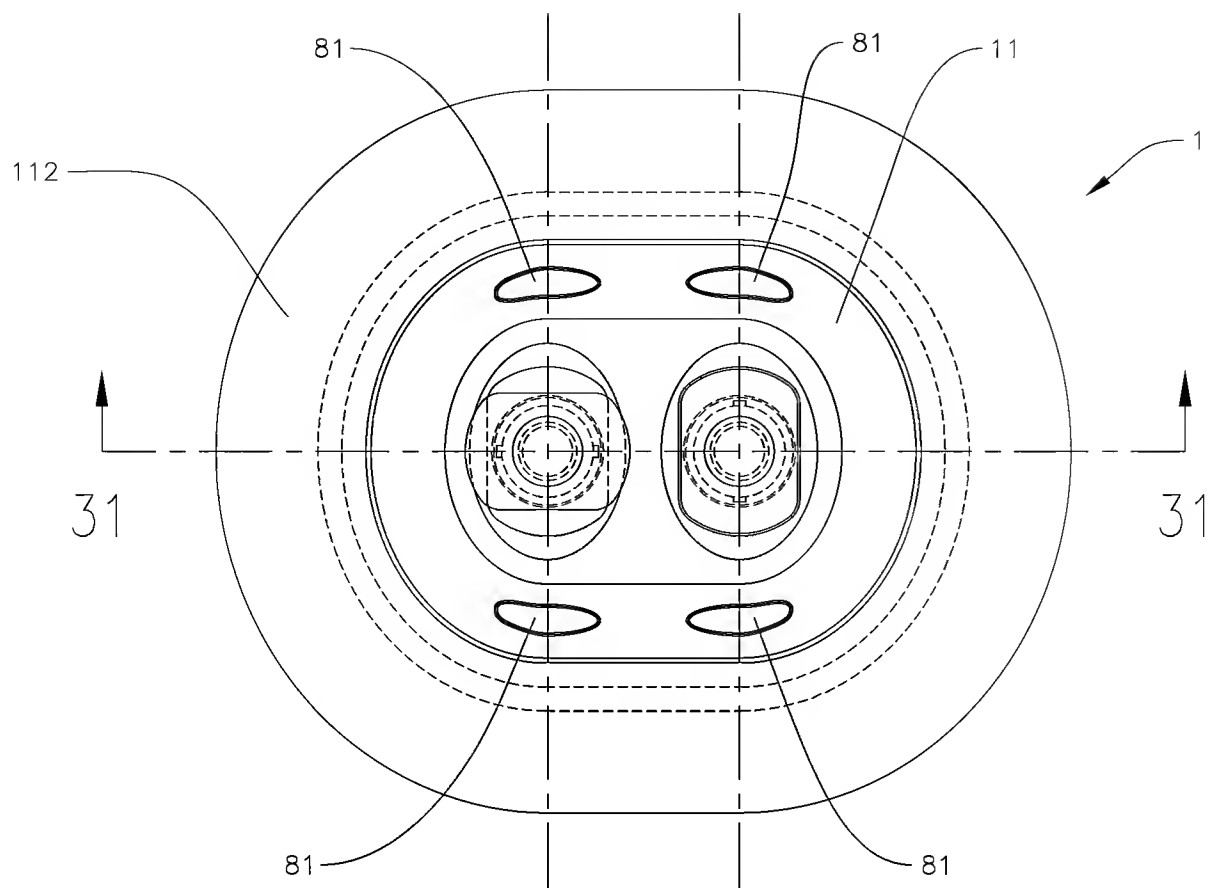


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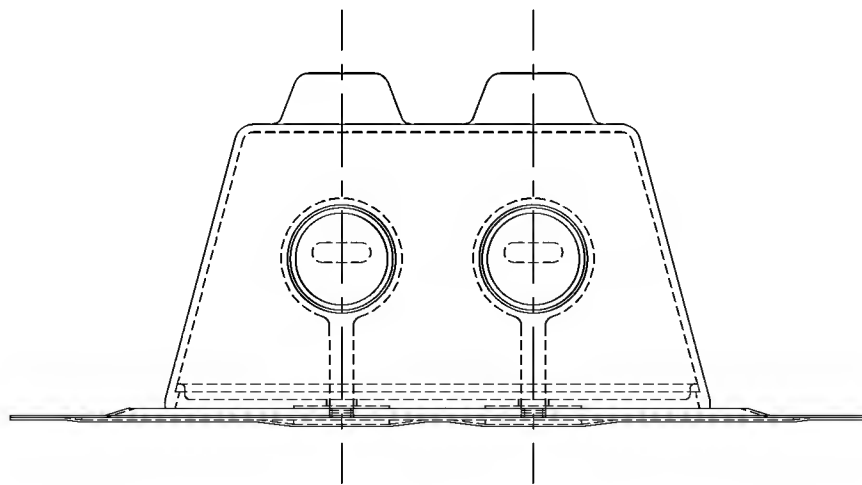


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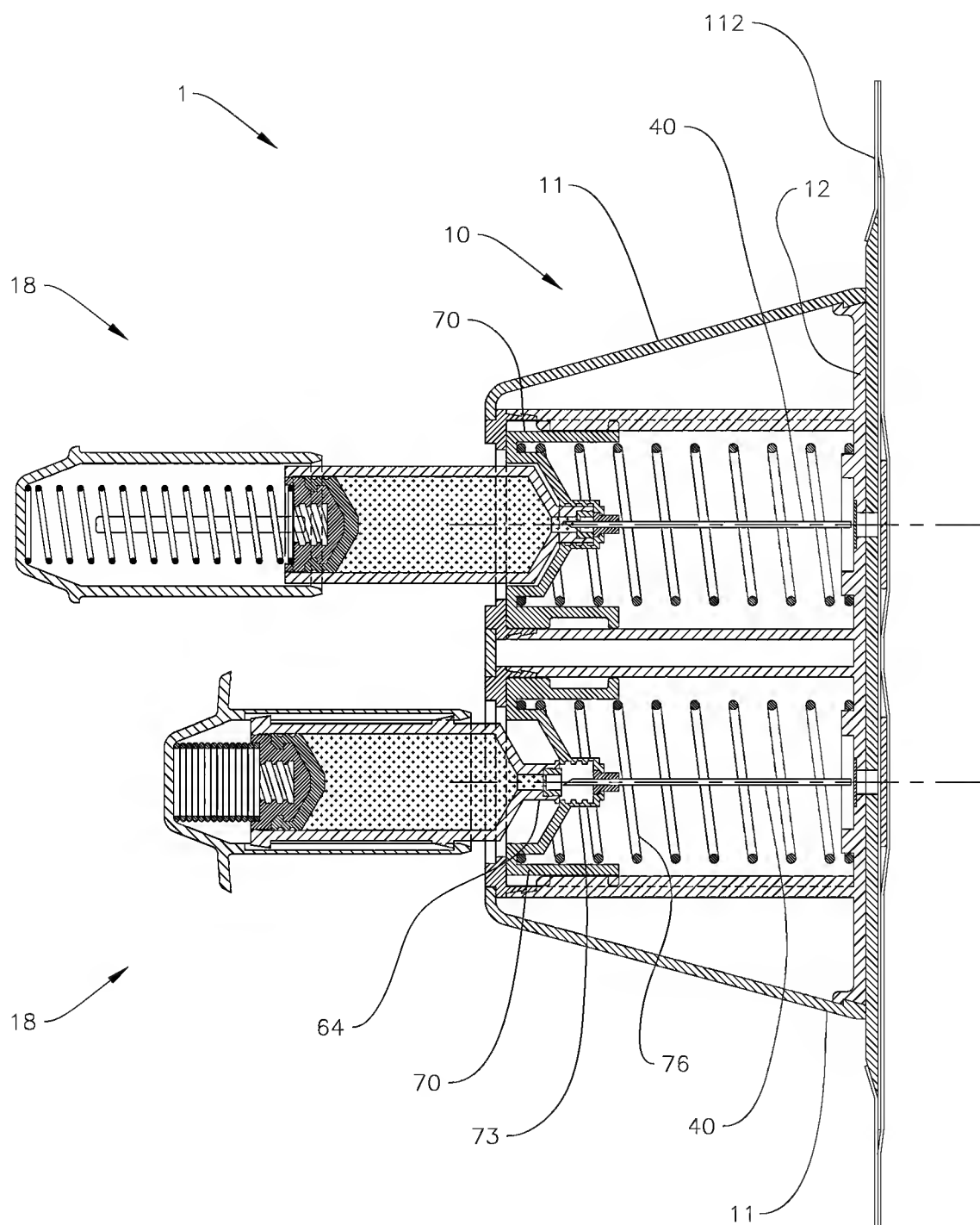


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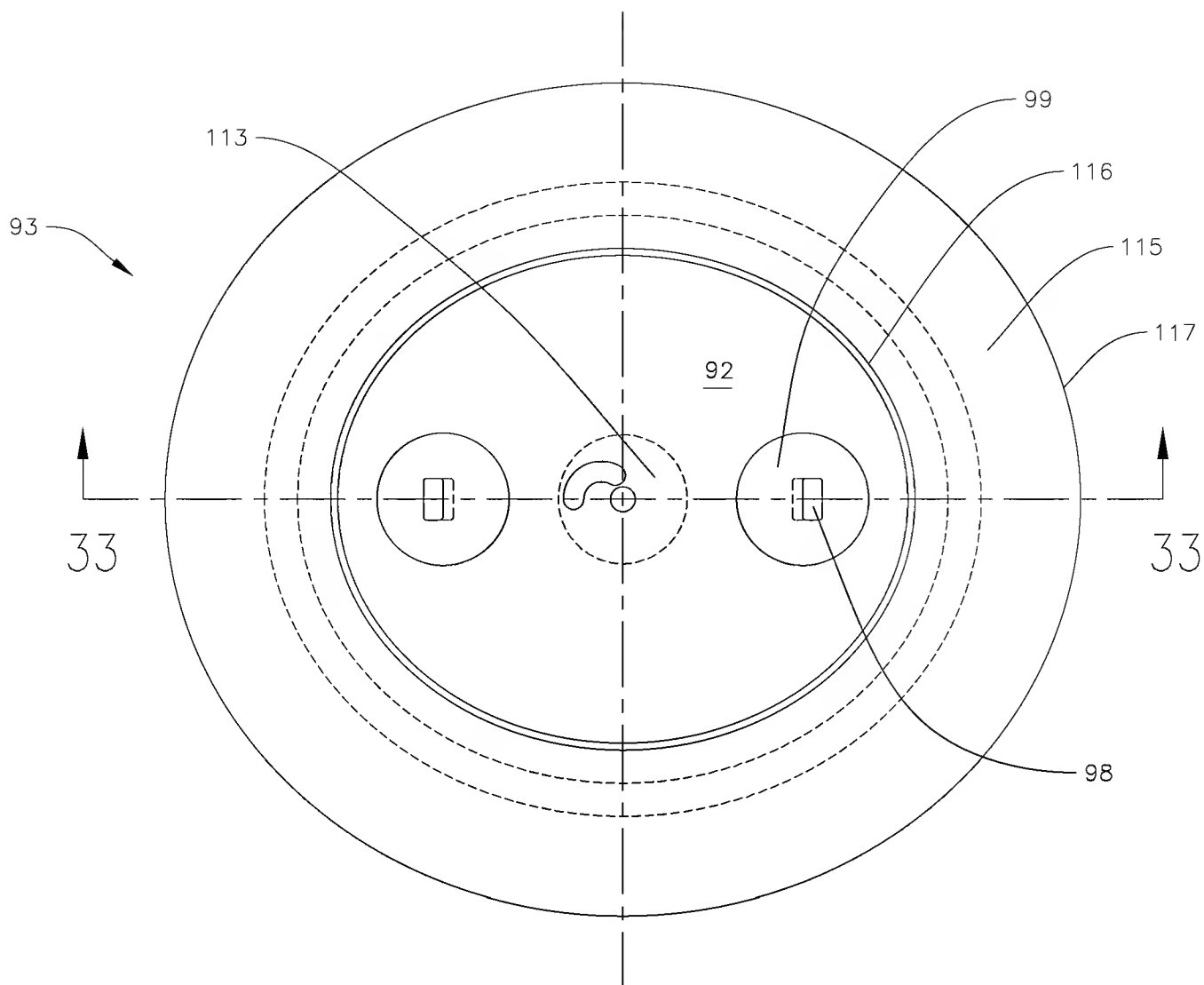


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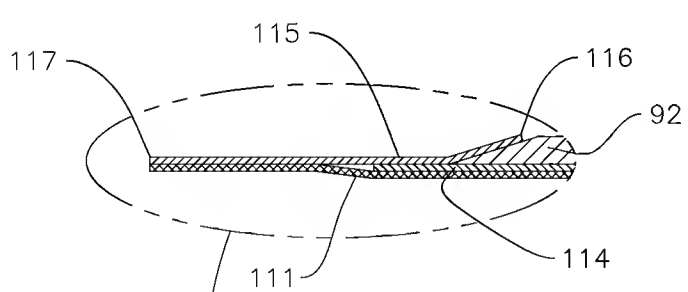


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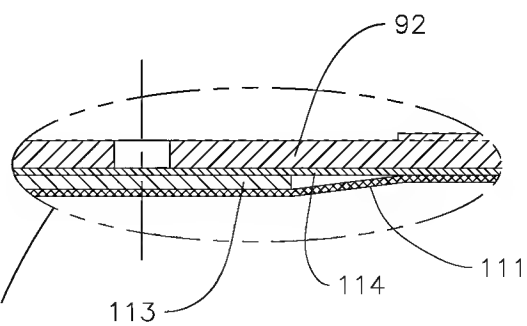


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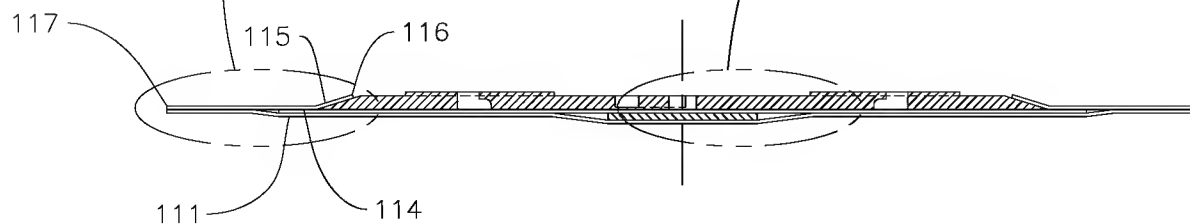


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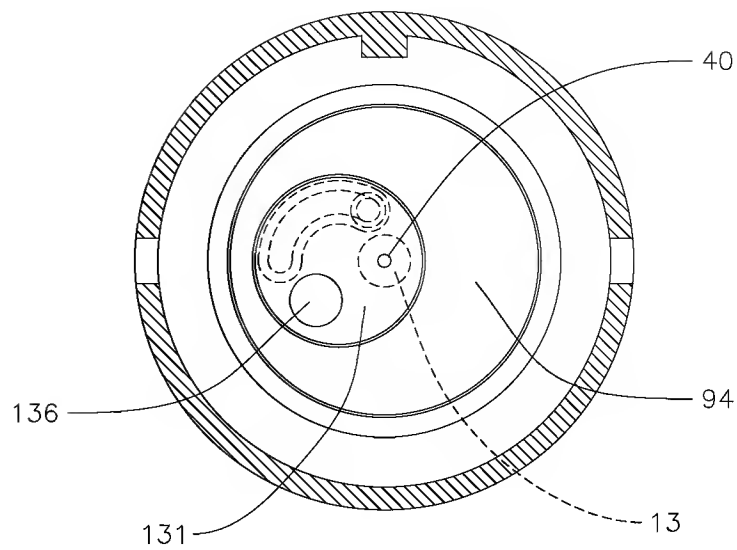


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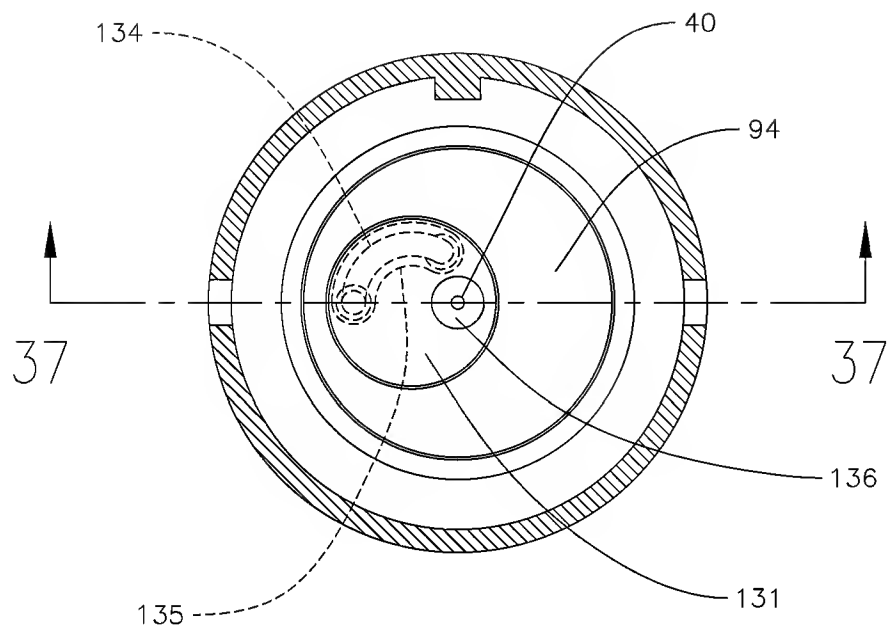


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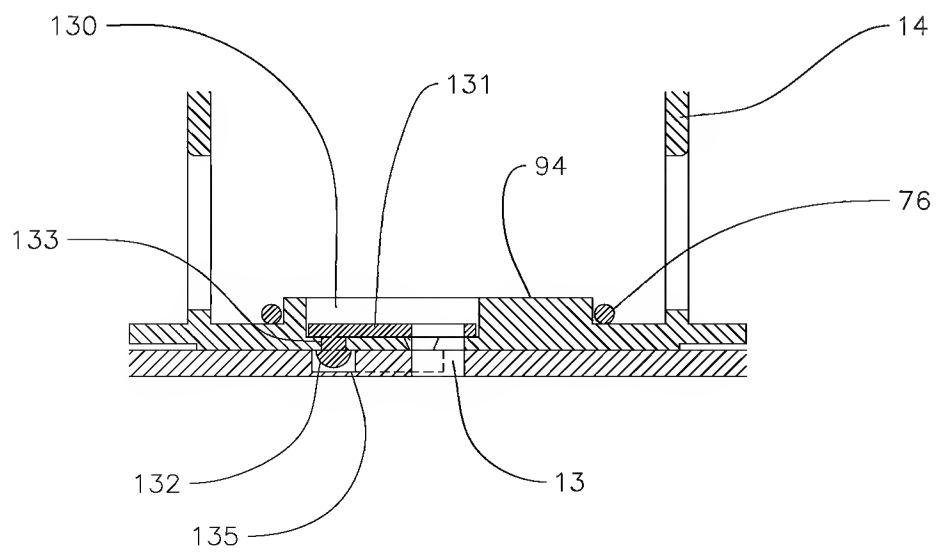


Fig. 37